

March 2015 PBAC OUTCOMES – 1ST TIME DECISIONS NOT TO RECOMMEND

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
<p>APREMILAST 10 mg, 20 mg and 30 mg tablets</p> <p>Otezla®</p> <p>Celgene Pty Ltd</p> <p>(Major submission)</p>	<p>Moderate to severe plaque psoriasis</p>	<p>The submission sought an Authority Required (STREAMLINED) listing for the treatment of moderate-to-severe plaque psoriasis in patients meeting certain criteria.</p>	<p>The PBAC rejected the submission on the basis that cost-effectiveness compared with cyclosporin treatment had not been adequately established at the price proposed in the submission. An incremental benefit in terms of comparative efficacy and safety over cyclosporin was not evident for apremilast and so it did not appear clinically appropriate to require patients to trial an additional line of therapy before being eligible for bDMARD therapy. Therefore, the cost-utility analysis approach to the economic modelling was not considered informative.</p> <p>There were no statistically significant differences in the number of patients achieving PASI 75 or PASI 50 improvement in those treated with apremilast (30 mg twice daily for 16 weeks, including titration) or cyclosporin (2.5 mg/kg for 10 weeks), and the point estimate from the indirect comparison in terms of PASI 50 tended towards inferiority.</p> <p>The proposed cost of treatment with apremilast was considerably higher than the cost of treatment with cyclosporin.</p>
		<p align="center">Sponsor Comment:</p>	<p>Celgene firmly believes Apremilast offers significant clinical advantages for patients with Psoriasis and Psoriatic arthritis and is disappointed with the PBAC outcome.</p> <p>Celgene is committed with continuing to work with the Department of Health and the PBAC to make Apremilast available for Australian patients.</p>
<p>APREMILAST 10 mg, 20 mg and 30 mg tablets</p> <p>Otezla®</p> <p>Celgene Pty Ltd</p> <p>(Major submission)</p>	<p>Psoriatic arthritis</p>	<p>The submission sought an Authority Required (STREAMLINED) listing for the treatment of severe active psoriatic arthritis in patients meeting certain criteria.</p>	<p>The PBAC rejected the submission on the basis of unacceptable cost-effectiveness compared with leflunomide at the price proposed and on the basis of a low clinical need for a treatment that would potentially delay treatment with more effective (but more costly) bDMARD therapy.</p> <p>There were no statistically significant differences in the number of patients achieving ACR20 response in those treated with apremilast or leflunomide over 24 weeks.</p> <p>The proposed cost of treatment with apremilast was considerably higher than the cost of treatment with leflunomide.</p>

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		Sponsor Comment:	<p>Celgene firmly believes Apremilast offers significant clinical advantages for patients with Psoriasis and Psoriatic arthritis and is disappointed with the PBAC outcome.</p> <p>Celgene is committed with continuing to work with the Department of Health and the PBAC to make Apremilast available for Australian patients.</p>
<p>ASUNAPREVIR 100 mg capsule, 56</p> <p>Sunvepra[®]</p> <p>Bristol-Myers Squibb Australia Pty Ltd</p> <p>(Major Submission)</p>	Hepatitis C	<p>The submission sought an Authority Required (STREAMLINED) listing for the treatment of chronic genotype 1b hepatitis C virus infection.</p> <p>Sponsor Comment:</p>	<p>The PBAC rejected the submission for the Authority Required (Streamlined) listing for asunaprevir for the treatment of chronic genotype 1b hepatitis C virus infection. While asunaprevir (in combination with daclatasvir) was an effective interferon-free treatment, the PBAC considered that this combination is inferior to other treatments for chronic hepatitis C recommended by the PBAC at the March 2015 meeting.</p> <p>Bristol-Myers Squibb is disappointed with the PBACs decision to reject DCV+ASV. However remains committed to working with the department to provide access to new medicines for HCV as soon as possible.</p>

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<p>BRENTUXIMAB VEDOTIN 50 mg powder for injection</p> <p>Adcetris®</p> <p>Takeda Pharmaceuticals Australia Pty Ltd.</p> <p>(Major Submission)</p>	<p>Hodgkin Lymphoma</p>	<p>The submission sought Section 100 (Efficient Funding of Chemotherapy) listing for brentuximab vedotin for the treatment of adult patients with relapsed or refractory CD30+ Hodgkin Lymphoma following autologous stem cell transplant. The submission also requested that the PBAC consider whether the Rule of Rescue is applicable.</p>	<p>The PBAC rejected the submission to extend the listing of brentuximab vedotin to the treatment of relapsed or refractory Hodgkin Lymphoma following autologous stem cell transplant because the clinical place was not well defined and the submission's estimate of cost effectiveness was not reliable. The PBAC also noted the low quality of the clinical data presented. Further, the PBAC was concerned that the range of restrictions proposed by the sponsor would exclude some patient groups who could derive significant benefit from this drug.</p> <p>The PBAC noted the high clinical need for effective treatments for Hodgkin Lymphoma.</p> <p>The PBAC considered that brentuximab vedotin is an effective treatment, but that the magnitude of the gains in progression-free survival and overall survival were difficult to quantify given the poor quality of the data submitted. The PBAC considered that brentuximab vedotin is not a cure, but rather provides a "bridge" to enable some patients to undergo a potentially curative allogeneic stem cell transplant. It also provides palliative benefit to responding patients who do not have an allogeneic stem cell transplant option.</p> <p>The PBAC considered that brentuximab vedotin is less toxic than salvage therapy, however based on the information presented in the submission, the PBAC was not able to reliably quantify the comparative harms of brentuximab vedotin compared with salvage chemotherapy.</p>
		<p align="center">Sponsor Comment:</p>	<p>Takeda Australia will continue to work with the PBAC to enable the listing of Adcetris on the PBS for Australian patients with relapsed or refractory Hodgkin lymphoma after autologous stem cell transplant.</p>

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<p>DEXAMETHASONE 700 µg implant</p> <p>Ozurdex®</p> <p>Allergan Australia Pty Limited</p> <p>(Major Submission)</p>	<p>Diabetic macular oedema</p>	<p>The submission sought an Authority Required (streamlined) listing for dexamethasone posterior segment drug delivery system (referred to in the submission as dexamethasone implant) for the treatment of vision impairment due to centre-involving diabetic macular oedema.</p>	<p>The PBAC rejected the submission to list dexamethasone implant for the treatment of diabetic macular oedema on the basis that the evidence presented did not conclusively establish clinical non-inferiority of dexamethasone implant compared with ranibizumab and bevacizumab.</p> <p>The PBAC considered that the eligible patient population and clinical place of dexamethasone implant were not well-defined. Although the intended PBS population was clarified as being patients with vision impairment due to centre-involving diabetic macular oedema who also have pseudophakic lens or who are also scheduled for cataract surgery, the PBAC noted that the TGA delegate and other regulatory agencies also contemplated second-line use by patients who are considered insufficiently responsive to, or unsuitable for, non-corticosteroid therapy.</p>
		<p align="center">Sponsor Comment:</p>	<p>Allergan is disappointed with the outcome. Allergan is committed to ensuring patients with diabetic macular oedema have access to dexamethasone implant. Allergan will engage with PBAC to understand and address the issues raised in the PBAC minutes.</p>

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<p>ETANERCEPT, injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL; injections 50 mg in 1 mL single use pre-filled syringes; injection 50 mg in 1 mL single use auto-injector, Enbrel[®], Pfizer Australia Pty Ltd (Major submission)</p>		<p>The submission sought to extend etanercept's current listing by adding a new general schedule Authority Required indication for the treatment of non-radiographic axial spondyloarthritis</p>	<p>The PBAC rejected the submission on the basis that although the trial data suggested short term efficacy, the available evidence did not enable PBAC to characterise the likely magnitude of benefit with respect to patient relevant outcomes additional to the ASAS 40 (such as disease progression) in patients with non-radiographic axial spondyloarthritis (nr-axSpA). Even if the natural history of this condition was well characterised, the short term data and economic analysis did not allow PBAC to define a population in whom treatment could be expected to be cost effective at the sponsor's asking price.</p> <p>On the basis of Trial 1031 presented by the submission, for every 100 patients treated with etanercept in comparison to placebo:</p> <ul style="list-style-type: none"> • Approximately 17 additional patients would have experienced response, in terms of the ASAS 40, over 12 weeks. • Between 0 and 9 additional patients would have experienced an eye disorder over 12 weeks. • Between 1 and 12 additional patients would have experienced injection site erythema over 12 weeks. • Between 2 and 11 additional patients would have experienced an injection site reaction over 12 weeks.
		<p>Sponsor Comment:</p>	<p>The sponsor is disappointed with the PBAC outcome and plans to work with the PBAC to make etanercept available for patients with nonradiographic axial spondyloarthritis.</p>

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<p>EVOLOCUMAB</p> <p>140 mg pre-filled injection pen</p> <p>Amgen Pty Ltd</p> <p>(Major Submission)</p>	Hypercholesterolaemia	The submission sought to open a dialogue regarding the potential future listing of evolocumab on the PBS for the treatment of hypercholesterolaemia.	<p>The PBAC rejected the request to list evolocumab for the treatment of hypercholesterolaemia on the basis of unestablished clinical place in therapy and the uncertainty surrounding its use in clinical practice.</p> <p>The PBAC noted that the submission was made under the TGA-PBAC parallel process with the TGA Delegate's consideration expected in late 2015. Accordingly, the PBAC noted that there were no TGA documents available during the time of PBAC consideration to determine the indication of the drug and its clinical place in therapy.</p>
		Sponsor Comment:	<p>The intent of submitting this dossier through the TGA-PBAC parallel process was to open a dialogue in good faith with the PBAC to work collaboratively and ensure the best interests of patients were served. Amgen intends to continue to work constructively and collaboratively with the PBAC to secure PBS listing of evolocumab for Australian patients.</p>

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<p>IDELALISIB, 100 mg and 150 mg tablet</p> <p>Zydelig[®],</p> <p>Gilead Sciences Pty Ltd.</p> <p>(Major submission)</p>	<p>chronic lymphocytic leukaemia</p>	<p>The submission sought Section 85 Authority Required listing for idelalisib for the second-line treatment of chronic lymphocytic leukaemia.</p>	<p>The PBAC rejected the submission to list idelalisib for the treatment of patients with chronic lymphocytic leukaemia because the patient population was not adequately defined, the nominated comparator was inappropriate, and the economic evaluation required amendment. Therefore the cost-effectiveness could not be estimated in the context of a drug with a high cost compared with current care.</p> <p>The PBAC considered that idelalisib is an active drug that provides an additional avenue of therapy for patients with relapsed chronic lymphocytic leukaemia for whom chemo-immunotherapy is not suitable.</p> <p>On the basis of direct comparison evidence presented by the submission, over a median duration of follow-up of 6.1 months, for every 100 patients treated with idelalisib plus rituximab in comparison to placebo plus rituximab:</p> <ul style="list-style-type: none"> • Approximately 39 fewer patients would have progressed disease. • Approximately 18 additional patients would have fever (pyrexia). <p>For every 100 patients treated with idelalisib plus rituximab, over a median duration of follow-up of 8.3 months, approximately 9 will experience significant diarrhoea and 4 or 5 will develop colitis, two side effects that were not seen in patients treated with rituximab alone</p>
		<p align="center">Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>IDELALISIB 100 mg and 150 mg tablet</p> <p>Zydelig[®],</p> <p>Gilead Sciences Pty Ltd.</p> <p>(Major submission)</p>	<p>Non-Hodgkin's lymphoma</p>	<p>The submission sought Section 85 Authority Required (STREAMLINED) listing for the treatment of indolent subtypes of B-cell non-Hodgkin's lymphoma in patients with progressive disease despite previous treatment.</p>	<p>The PBAC rejected the submission to list idelalisib for the treatment of patients with indolent Non-Hodgkin's Lymphoma on the basis that the comparative effectiveness could not be established because the submission had not provided information about a comparable population treated with best supportive care. Therefore the cost-effectiveness could not be estimated.</p> <p>The PBAC agreed that there is a high unmet clinical need for an effective treatment for patients with indolent Non-Hodgkin's Lymphoma refractory to both rituximab and an alkylating agent. However, the PBAC considered that the application was deficient, because the data were of poor quality and did not provide a reliable basis for decision-making.</p> <p>In the absence of suitable data to inform the effectiveness of best supportive care, the comparative efficacy and safety of idelalsib could not be estimated.</p>
		<p align="center">Sponsor Comment:</p>	<p>The application relied on a single-arm study and while Gilead acknowledges a single arm trial is not an ideal basis for decision making, Gilead considers that in this highly heterogenous population who have exhausted treatment options, the study design was appropriate and well conducted despite the obvious limitations.</p>
<p>IMATINIB 100 mg and 400 mg tablets (as mesylate)</p> <p>Glivec[®], Novartis</p> <p>Pharmaceuticals Australia Pty Ltd</p>	<p>Gastrointestinal stromal tumor</p>	<p>The submission sought to change the pack size for imatinib for the treatment of patients with gastrointestinal stromal tumor in both metastatic and adjuvant settings.</p>	<p>The PBAC advised the Minister that there is no community need for the listing of alternative pack sizes of imatinib, namely 56 tablets per pack for 100 mg strength, and 28 tablets per pack for 400 mg strength, for the treatment of patients with gastrointestinal stromal tumor in both metastatic and adjuvant settings.</p>
		<p align="center">Sponsor Comment:</p>	<p>The sponsor had no comment.</p>

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<p>LIGNOCAINE 5% patch: dermal, 30</p> <p>Versatis[®],</p> <p>bioCSL Pty Ltd</p> <p>(Major submission)</p>	<p>Post-herpetic neuralgia</p>	<p>The submission sought Authority Required (STREAMLINED) listing for lignocaine 5% w/w dermal patch for the treatment of post-herpetic neuralgia.</p>	<p>The PBAC rejected the request to list lignocaine patch for the treatment of patients with post-herpetic neuralgia on the basis of uncertain cost-effectiveness compared with pregabalin.</p> <p>The PBAC considered that there is a potential clinical need for the lignocaine patch for the treatment of post-herpetic neuralgia and acknowledged the safety and quality use of medicine issues relating to the use of systemic therapies for this condition. However, the PBAC considered that the submission did not provide a confident basis that recommending lignocaine at the requested price would be cost-effective.</p> <p>The PBAC noted that non-inferiority between lignocaine patch and pregabalin was not demonstrated based on the pre-defined non-inferiority margin for the post-herpetic neuralgia and diabetic polyneuropathy population in the pivotal trial KF10004/03. Given that the trial failed the primary outcome, the PBAC considered that subgroup analyses and analyses of secondary outcomes were unreliable and should be interpreted with caution.</p> <p>The PBAC considered that while lignocaine patch appeared to be associated with fewer adverse events and discontinuations due to adverse events, compared with pregabalin during the first 4 weeks, differences in the safety profile were likely to be overestimated due to the open-label design of the trial and that patients who discontinued pregabalin due to adverse events during the comparative phase were allowed to switch to lignocaine.</p>

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		Sponsor Comment:	bioCSL is disappointed with the outcome but welcomes the PBAC's acknowledgement of the potential clinical need for VERSATIS which offers a topical treatment option for post herpetic neuralgia, a debilitating condition occurring predominantly in the elderly. bioCSL considers undue weight was placed on the results of the pivotal trial not meeting the pre-defined non-inferiority outcome in the overall per-protocol trial population which included patients with diabetic polyneuropathy, a condition for which VERSATIS is not registered in Australia. bioCSL also notes that the differences in safety profile between VERSATIS and pregabalin reflect the topical versus systemic nature of the two therapies.
<p>NETUPITANT /PALONOSETRON netupitant 300 mg + palonosetron 500 mcg capsule, 1</p> <p>Akynzeo[®], Specialised Therapeutics</p>	Acute and delayed chemotherapy induced nausea and vomiting	<p>The submission sought Authority Required (STREAMLINED) listing for netupitant with palonosetron fixed dose combination for the prevention of acute and delayed chemotherapy induced nausea and vomiting (1-5 days after initiating chemotherapy) associated with patients scheduled to receive:</p> <ul style="list-style-type: none"> • Highly emetogenic chemotherapy • Anthracycline plus cyclophosphamide chemotherapy for patients with breast cancer, or • Moderately emetogenic chemotherapy with a prior episode of chemotherapy induced nausea and vomiting. <p>Sponsor Comment:</p>	<p>The PBAC rejected the submission to list netupitant with palonosetron on the PBS for the prevention and treatment of chemotherapy induced nausea and vomiting. In making its recommendation, the PBAC considered that there was no unmet clinical need for this product, and that there was a lack of evidence of the effectiveness of netupitant with palonosetron for patients scheduled to receive moderately emetogenic chemotherapy. The evidence also did not reflect the appropriate comparative use, as aprepitant in combination with a serotonin receptor antagonist is not the appropriate comparator for patients scheduled to receive moderately emetogenic chemotherapy.</p> <p>The sponsor had no comment.</p>

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<p>NINTEDANIB 100 mg capsule, 60; 150 mg capsule, 60</p> <p>Ofev[®]</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>(Major Submission)</p>	<p>Idiopathic pulmonary fibrosis (IPF)</p>	<p>To submission sought Authority Required listing for nintedanib for treatment of idiopathic pulmonary fibrosis.</p>	<p>The PBAC rejected the request to list nintedanib for the treatment of patients with IPF on the basis of an uncertain estimate of comparative effectiveness, as measured by the effect on clinically relevant outcomes, including acute IPF exacerbations and overall survival, and a resulting very high and uncertain estimate of cost effectiveness.</p>
		<p align="center">Sponsor Comment:</p>	<p>The Sponsor had no comment.</p>
<p>NINTEDANIB 100 mg capsule, 60; 150 mg capsule, 60</p> <p>Ofev[®],</p> <p>Boehringer Ingelheim Pty Ltd</p> <p>(Major Submission)</p>	<p>Non-small cell lung cancer (NSCLC)</p>	<p>The submission sought Authority Required listing for nintedanib in combination with docetaxel for second line treatment of non-small cell lung cancer in patients with adenocarcinoma histology.</p>	<p>The PBAC rejected the request to list nintedanib (in combination with docetaxel) for the treatment of patients with NSCLC on the basis that the submission did not demonstrate non-inferior effectiveness compared with pemetrexed. In addition, the cost utility analysis presented in the submission was inconsistent with the clinical claim of non-inferior efficacy and inferior safety of nintedanib (in combination with docetaxel) to pemetrexed.</p>
		<p align="center">Sponsor Comment:</p>	<p>The Sponsor had no comment.</p>

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<p>OXYCODONE HYDROCHLORIDE 5 mg, modified release tablet, Oxycodone Sandoz[®], Sandoz Pty Ltd (Minor submission)</p>	<p>Pain</p>	<p>The submission sought PBS listing of a 5 mg strength of modified release oxycodone.</p>	<p>The PBAC rejected the proposed General schedule listing of the oxycodone 5 mg strength. The PBAC noted that another sponsor's 5mg presentation of oxycodone had been removed from the PBS at the request of that sponsor. The PBAC recalled that as a standard part of a request to delist a product from the PBS, it must be established that there is no pressing clinical need for the product in question. Having been satisfied that this was the case for oxycodone 5mg, the PBAC considered that this submission had not established a convincing argument that a clinical need for this strength now existed.</p>
		<p>Sponsor Comment:</p>	<p>The sponsor had no comment.</p>
<p>PNEUMOCOCCAL CONJUGATE VACCINE 13-VALENT ADSORBED pre-filled syringe, 0.5 mL Prevenar 13[®], Pfizer (Major submission)</p>	<p>pneumococcal pneumonia and invasive pneumococcal</p>	<p>The major submission sought National Immunisation Program listing for 13-valent pneumococcal conjugate vaccine (13vPCV) for the prevention of pneumococcal pneumonia and invasive pneumococcal disease in adults.</p>	<p>The PBAC rejected the submission to list pneumococcal conjugate vaccine, 13-valent absorbed (13vPCV) for the prevention of pneumococcal disease on the National Immunisation Program (NIP) for the requested population on the basis of uncertain cost-effectiveness. While the PBAC considered that 13vPCV is likely to be superior to the first dose of pneumococcal polysaccharide vaccine, 23-valent (23vPPV) in terms of prevention of vaccine type pneumonia, the submission did not provide a confident basis that recommending 13vPCV at the requested price would be cost-effective.</p> <p>Based on a qualitative indirect comparison using placebo/no vaccine as the common comparator, it was not clear whether 13vPCV was worse or better than 23vPPV in the prevention of invasive pneumococcal disease.</p> <p>On the basis of a trial comparing 13vPCV with placebo, 1,057 adults aged ≥65 years would need to be vaccinated with 13vPCV to prevent one case of vaccine type pneumonia. Clinical trial data assessing the effect of 23vPPV in the prevention of vaccine type pneumonia were not available.</p> <p>On the basis of head-to-head immunogenicity trials and the presented indirect comparison, in subjects naïve to 23vPPV the frequency of adverse effects appeared to be comparable.</p>

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		Sponsor comment:	Pfizer Australia is disappointed with the outcome. Due to the significant burden of pneumococcal pneumonia in older Australians, the Sponsor is willing to work with the PBAC to ensure timely and equitable access to Prevenar 13.

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<p>REGORAFENIB 40 mg tablet, 84</p> <p>Stivarga[®],</p> <p>Bayer Australia Ltd</p> <p>(Major Submission)</p>	<p>Gastrointestinal stromal tumours</p>	<p>The submission sought section 85 Authority required listing for regorafenib for treatment of gastrointestinal stromal tumours.</p>	<p>The PBAC rejected the request to list regorafenib for the treatment of patients with gastrointestinal stromal tumours on the basis of uncertain efficacy and cost-effectiveness.</p> <p>On the basis of direct randomised evidence presented by the submission, for patients treated with regorafenib in comparison with best supportive care, there would be:</p> <ul style="list-style-type: none"> • Approximately 3.9 months difference in median progression-free survival. • An unknown possible difference in median overall survival. <p>On the basis of direct randomised evidence presented by the submission, for every 100 patients treated with regorafenib in comparison with best supportive care:</p> <ul style="list-style-type: none"> • Approximately 51 additional patients would experience at least one treatment-emergent adverse event of at least Grade 3 severity. • Approximately 20 additional patients would experience a hand-foot skin reaction of at least Grade 3 severity. • Approximately 20 additional patients would experience hypertension of at least Grade 3 severity. <p>The PBAC accepted that regorafenib provides a clinical benefit to patients in terms of progression-free survival but considered that any increase in overall survival was unknown and the adverse effect profile of regorafenib was not adequately reflected in the sponsor's economic analysis. Given the small clinical benefit due to progression-free survival and the unfavourable safety profile of regorafenib, the PBAC considered that the incremental cost effectiveness per quality-adjusted life-year gained was highly uncertain.</p>
		<p>Sponsor Comment:</p>	<p>The Sponsor intends to continue working with the PBAC to make regorafenib available to those Australian patients that could benefit from the product</p>

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RIBAVIRIN 400mg and 600mg Ibavyr® Clinect (Major Submission)	Chronic hepatitis C (CHC).	The submission sought a Section 100 Authority Required (STREAMLINED) listing for ribavirin for the treatment of chronic hepatitis C (CHC).	The PBAC rejected the submission for the Section 100 (Highly Specialised Drugs Program) Authority Required (Streamlined) listing for ribavirin for the treatment of chronic hepatitis C Genotype 2 and 3. The PBAC noted the clinical need for a stand-alone ribavirin for the treatment of genotype 2 and 3 patients in combination with sofosbuvir, however the submission had not justified the incremental cost effectiveness of ribavirin compared to the currently listed ribavirin based items.
		Sponsor Comment:	Clinect Pty Ltd is committed to working with the PBAC to secure reimbursement of IBAVYR® to assist Australians suffering with Chronic hepatitis C (CHC). Clinect will be lodging all necessary materials in April 2015 so that IBAVYR® can be reconsidered at the July 2015 PBAC meeting.