JULY 2015 PBAC OUTCOMES - DEFERRALS

DRUG NAME, FORM(S), STRENGTH(S), SPONSOR, TYPE OF SUBMISSION	DRUG TYPE AND USE	LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION	PBAC OUTCOME
BUPRENORPHINE 15 mg/hour patch 25 mg/hour patch 30 mg/hour patch 40 mg/hour patch NORSPAN® Mundipharma Pty Ltd New listing (Matter outstanding from March 2015 PBAC meeting)	Pain	To list additional strengths for the same indications currently applying to the existing patches.	The PBAC considered that it would not be appropriate to add further strengths of buprenorphine to the PBS without a consolidated view of what combination of strengths of these drugs would be most appropriate for Australian clinical practice. The PBAC requested that the Department undertake further consultation with relevant clinical and professional organisations regarding the clinical place of different opioid strengths.
		Sponsor Comment:	The sponsor had no comment.
IVACAFTOR 150 mg tablet, 56 KALYDECO® Vertex Pharmaceuticals Pty Ltd Change to listing (Minor Submission)	Cystic fibrosis	Amendment to the PBS restriction to enable a higher dose of ivacaftor in patients who are concomitantly on a strong CYP3A4 inhibitor.	The PBAC deferred making a recommendation. The PBAC recalled that previous amendments to the PBS restriction had been preceded by supporting changes in the approved TGA product information (PI). The PBAC requested that the Secretariat seek advice from the Therapeutic Goods Administration about the status of the PI for ivacaftor.
		Sponsor Comment:	The sponsor had no comment.

OXYCODONE with NALOXONE 2.5 mg/1.25 mg 15 mg/7.5 mg 30 mg/15mg TARGIN® Mundipharma Pty Ltd New listing (Matter outstanding from March 2015 PBAC meeting)	Pain	To list additional strengths for the same indications currently applying to the existing tablets.	The PBAC considered that it would not be appropriate to add further strengths of oxycodone + naloxone to the PBS without a consolidated view what combination of strengths of these drugs would be most appropriate for Australian clinical practice. The PBAC requested that the Department undertake further consultation with relevant clinical and professional organisations regarding the clinical place of different opioid strengths.
		Sponsor Comment:	The sponsor had no comment.
RIBAVIRIN 400 mg tablet, 28 600 mg tablet, 28 IBAVYR® Clinect Pty Ltd New listing (Minor Submission)	Hepatitis C	Re-submission for Authority Required (STREAMLINED) listing for the treatment of chronic hepatitis C (CHC) viral infection in patients 18 years or older who have compensated liver disease.	The PBAC deferred its decision for the Authority Required listing of ribavirin for the treatment of CHC. The PBAC reiterated the clinical need for stand-alone ribavirin for the treatment of genotype 2 and 3 patients, noting the large number of comments and presentations from patients, health care professionals and organisations highlighted the benefits of the availability of new treatments, particularly interferon-free regimens. The PBAC noted that interferon-free treatments for CHC have been recently, or are currently being, assessed by the TGA. The PBAC was concerned that it has not been established how ribavirin would be used in association with other all oral interferon-free regimens in Australia, compared with international guidelines and that the proposed listing may inappropriately restrict availability of ribavirin to patients infected with other CHC genotypes.
		Sponsor Comment:	The sponsor was disappointed that the significantly revised pricing proposed in its resubmission, which was demonstrably based on a previously accepted cost minimisation outcome, was again not accepted by the PBAC. The PBAC states ‘uncertainty’ about how to make ribavirin available for future CHC treatments. However the proposed listing of ribavirin is reflective of the current approved treatment regimens presented for consideration at this cycle. If the ‘stepwise’ approach to listings, as discussed at prior CHC Stakeholder meetings is adopted to meet the evolution of CHC therapy, the stand alone ribavirin listing could be extended accordingly by the PBAC and sponsor. The TGA approved

			indication of IBAVYR® is for 'the treatment of CHC in adults, in combination with other oral agents' and should present no obstacle in such a process.
SIMEPREVIR 150mg capsule, 7 OLYSIO® Janssen-Cilag Pty Ltd. Change to listing (Major submission)	Hepatitis C	The submission requested a Section 100 (Highly Specialised Drugs Program) Authority Required (Streamlined) listing for simeprevir in combination with sofosbuvir (SMV+SOF) for the treatment of patients with genotype 1 chronic hepatitis C (CHC) infection who have compensated liver disease, irrespective of previous treatment history.	The PBAC recommended deferral of the submission given that a positive TGA Delegate's Overview was not available at the time of consideration. The PBAC was of a mind to recommend listing of simeprevir, in combination with sofosbuvir, but decided to wait for finalisation of the TGA registration process to determine the circumstances of listing. The PBAC considered that the conditions and circumstances of the listing of simeprevir in combination with peginterferon alfa and ribavirin should be reassessed to align this listing with a listing in combination with sofosbuvir.
		Sponsor Comment:	Janssen are continuing to work towards achieving a PBS listing for simeprevir as an interferon-free combination with sofosbuvir for genotype 1 Hepatitis C virus infection.
USTEKINUMAB 45 mg/0.5 mL injection, 1 STELARA® Janssen-Cilag Pty Ltd Change to listing (Minor Submission)	Psoriatic arthritis	Re-submission for Authority Required listing for the treatment of severe active psoriatic arthritis	The PBAC deferred making a recommendation regarding the request to list ustekinumab as an Authority Required benefit for the treatment of psoriatic arthritis, as acceptance of the submission's claim that ustekinumab is non-inferior to certolizumab pegol and inferior to adalimumab required the PBAC to accept that certolizumab pegol is also inferior to adalimumab, a finding which would be inconsistent with the PBAC recommendation for certolizumab pegol from November 2014. The PBAC considered this issue would need to be resolved before it could consider making a recommendation to list ustekinumab for psoriatic arthritis.
		Sponsor Comment:	Janssen is committed to continuing to work with the PBAC to achieve funding of this medicine as an alternative to PBS listed TNF alpha inhibitor therapies for Australians living with severe psoriatic arthritis.