JULY 2018 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
LENVATINIB Capsule 4 mg (as mesilate) Lenvima® Eisai Australia Pty Ltd Change to listing (Major Submission)	Hepatocellular carcinoma	To request an Authority Required (STREAMLINED) listing for the treatment of advanced unresectable hepatocellular carcinoma.	The PBAC deferred making a recommendation to list lenvatinib for the treatment of unresectable hepatocellular carcinoma (HCC). However, the PBAC was of a mind to recommend lenvatinib pending the provision of the relevant TGA delegate's overview. The PBAC noted that lenvatinib would provide patients with HCC an alternative to sorafenib as a first line therapy. The PBAC considered that lenvatinib was non-inferior in terms of effectiveness and safety compared with sorafenib, noting that there were differences between the safety profiles of the two drugs. The PBAC considered that the cost-minimisation analysis was reasonable when the mean treatment durations and mean doses of lenvatinib and sorafenib were used so that the treatment cost per patient was the same for both treatments.
		Sponsor Comment:	Eisai Australia Pty Ltd is pleased that the PBAC was of a mind to recommend lenvatinib as a treatment for HCC and will work with the Department to progress PBS listing as soon as possible following TGA registration.
OSIMERTINIB Tablet 40 mg Tablet 80 mg Tagrisso® Astra Zeneca Pty Ltd New listing (Major Submission)	Locally advanced (Stage IIIB) or metastatic (Stage IV) epidermal growth factor receptor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC)	Resubmission to request an Authority Required listing for the treatment of patients with locally advanced or metastatic epidermal growth factor (EGFR) T790M mutation positive non-small cell lung cancer (NSCLC) who have progressed on or after prior treatment with an EGFR tyrosine kinase inhibitor (TKI).	The PBAC deferred making a recommendation to list osimertinib for the treatment of EGFR T790M mutation positive non-small cell lung cancer. The Committee requested further clarification from the sponsor regarding the proposed risk sharing arrangement and utilisation estimates. In deferring its decision, the PBAC acknowledged that osimertinib treatment provided a clinical benefit to some patients, but considered that the magnitude of incremental overall survival benefit was difficult to determine from the evidence presented in the submission. The PBAC advised that although osimertinib treatment was effective compared with platinum chemotherapy in relation to progression free survival (PFS), the magnitude of the overall survival (OS) benefit of osimertinib treatment compared with platinum chemotherapy remained uncertain. The PBAC noted that the comparative harms of osimertinib treatment were unchanged from the previous submission, and advised that it was superior in safety compared with platinum chemotherapy. The PBAC considered that there was uncertainty in the OS data and statistical methodology to adjust for treatment crossover (where participants originally treated with platinum chemotherapy started taking osimertinib) in the trial. These concerns consequently introduced

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			substantial uncertainty into the resubmission's economic model. The PBAC, noting the sponsor's risk sharing agreement proposal to mitigate this and other concerns about the cost-effectiveness of osimertinib. The PBAC advised that further information would be required regarding the patient numbers, estimated expenditure, financial caps and impact on the cost-effectiveness.
		Sponsor Comment:	The sponsor had no comment.
PEGFILGRASTIM Injection 6 mg in 0.6 mL single use pre-filled syringe Fulphila® Alphapharm Pty Ltd New listing (Minor Submission)	Chemotherapy-induced neutropenia	To request a Section 100 (Highly Specialised Drug) Authority Required (STREAMLINED) listing of this biosimilar brand for all indications for which the reference biologic is currently PBS listed.	The PBAC deferred making a recommendation regarding the listing of biosimilar pegfilgrastim (Fulphila ®) pending its TGA approval. The PBAC advised it was appropriate to consider the comparative efficacy and safety to the reference brand, Neulasta®, once the final conditions of TGA registration were known.
		Sponsor Comment:	The sponsor had no comment.