

**MAY 2020 PBAC MEETING – OTHER MATTERS**

<b>DRUG, SPONSOR, TYPE OF SUBMISSION</b>	<b>DRUG TYPE OR USE</b>	<b>LISTING REQUESTED BY SPONSOR / PURPOSE OF SUBMISSION</b>	<b>PBAC OUTCOME</b>
Update on the review of the Palliative Care Schedule and plan for consultation	Palliative Care	To update the PBAC on the progress of the review of the Palliative Care Schedule (PCS) to date and seek PBAC's agreement to the proposed approach to further targeted consultation with the Royal College of General Practitioners and Palliative Care Australia	The PBAC noted the work undertaken on the review of the PCS to date. The PBAC acknowledged previous correspondence from stakeholders on the PCS and considered that further targeted consultation with key stakeholder organisations, the Royal College of General Practitioners and Palliative Care Australia should be undertaken to seek their current views in relation to the PCS and the individual medicine listings it contains given recent changes to opioid listings. The PBAC noted that the outcome of the stakeholder consultation and the internal review will be presented to PBAC for its consideration and subsequent advice to the Minister.
Consideration for an Appendix to the PBAC Guidelines relating to tumour biomarker guided site agnostic therapies	Various	To consider the development of an Appendix to the existing PBAC guidelines to provide applicants with additional guidance on the issues that would require consideration in PBAC submissions for tumour biomarker-guided site-agnostic therapies.	<p>The PBAC noted the March 2019 correspondence from the Minister requesting a range of activities in relation to subsidised access to medicines for multiple cancer indications on the PBS. This included a request that the Department support the PBAC in its work to develop an Appendix to the PBAC Guidelines to provide information on possible approaches to multi-indication submissions within the existing legislative framework.</p> <p>The PBAC considered that a high level Appendix to its existing guidelines would be appropriate to provide applicants with additional guidance on the issues that would require consideration in PBAC submissions for tumour biomarker-guided site-agnostic therapies. The PBAC anticipated that a number of submissions for tumour biomarker guided site-agnostic therapies will be forthcoming, noting that some tumour-agnostic therapies have received overseas regulatory approval and a number of tumour biomarkers were currently being investigated for targeted therapies. The PBAC maintained its 2018 advice to the Minister that its preferred position is not to implicitly or explicitly endorse an approach which preferences recommendations for medicines (or a particular class of medicines) for one disease or sub-set of diseases over other equally devastating diseases. The PBAC advised that the Appendix should make clear that the evidence requirements for tumour biomarker-guided site agnostic therapies would be no different to that for other medicines considered in the current PBS system and that the existing legislative and policy framework for PBAC decision-making would still apply to these therapies.</p>

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Age restrictions on inhaled corticosteroid (ICS) + long-acting beta2 agonist (LABA) fixed dose combination products	Asthma	For the PBAC to consider the outstanding matters of concern regarding its December 2019 recommendation for new PBS listings of ICS+LABA FDC products for children <12 years who have failed with fluticasone propionate + salmeterol.	<p>The PBAC clarified the intention of its December 2019 recommendation in relation to the appropriate use of inhaled corticosteroid (ICS) + long-acting beta agonist (LABA) fixed dose combination (FDC) products in children under the age of 12 who have experienced fluticasone propionate + salmeterol failure.</p> <p>The PBAC affirmed its December 2019 recommendation for separate Authority Required (STREAMLINED) listings for all budesonide + formoterol FDC products (except the 400/12 mcg strength) that are silent on age and restrict use to patients who have failed fluticasone propionate + salmeterol. The PBAC reaffirmed its previous recommendation that prescribing for these second-line listings would be limited to respiratory specialists and paediatricians.</p> <p>The PBAC considered that this would provide an alternative treatment for a small population of children under the age of 12 who have failed to respond to fluticasone propionate + salmeterol. The PBAC considered that these new listings should not be extended to other ICS+LABA FDC products given the lack of clinical evidence on use of these products in this paediatric population.</p>
SOMATROPIN  Various forms and brands  Endocrine Society of Australia	Severe growth hormone deficiency (GHD)	To consider the request from the Endocrine Society of Australia in relation to changing the current somatropin restrictions to allow growth hormone dose reduction for patients with demonstrated GHD with an elevated IGF-1 level without treatment interruption.	The PBAC recommended amending the current somatropin restrictions so that patients would be eligible for continuing treatment with somatropin for severe GHD, irrespective of IGF-1 level, provided that the continuing treatment is prescribed by an endocrinologist. The PBAC considered that growth hormone replacement therapy should only be prescribed by an endocrinologist.
TERBINAFINE  Tablet 250 mg (as hydrochloride)  All brands  Royal College of Pathologists of Australasia	Onychomycosis	To consider the request from the Royal College of Pathologists of Australasia to change to the restriction wording of terbinafine to capture all appropriate methods for confirming dematophyte infection.	The PBAC recommended the clinical criteria relating to the diagnosis of dermatophyte infection for terbinafine 250 mg tablets for onychomycosis be changed to a single criterion of "dermatophyte infection confirmed by an Approved Pathology Provider" to ensure that all appropriate methods of diagnosis are captured.

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PBS Process Improvements project update	N/A	To update the PBAC on the outcomes of the first two trials of standardised redactions of public summary documents (PSDs), provide the PBAC with the final redaction criteria for standardised redactions to PSDs for noting, and update the PBAC on the implementation timelines for standardised redactions of PSDs.	<p>The PBAC noted the update on the transparency reforms related to standardised redactions to PSDs. The PBAC noted the extensive consultation with industry over the last 12 months and the outcomes of the first two trials of standardised redactions. The PBAC endorsed the subsequent revisions to section 7.4 Procedure Guidance, and noted the Procedure Guidance and supporting guidance document has been published and made available in sufficient time for applicants intending to submit to the November 2020 PBAC meeting.</p> <p>The PBAC noted the updates to the implementation timelines, specifically that process changes (a single opportunity to request redactions) for PSDs will be compulsory from and including July 2020 PSDs and that the standardised redaction criteria will be formally applied to all PSDs from and including November 2020 PSDs.</p> <p>The PBAC reiterated its May 2019 advice on the importance of these transparency reforms and noted that it strongly supported minimal redactions in PSDs and would prefer all clinical information relevant to its decision making to be publically available. The PBAC also noted that these changes are strongly supported by consumers. The PBAC acknowledged residual industry concerns related to the intended changes, and that the Department has agreed that industry will monitor any unintended consequences of the changes, with an opportunity for these to be reviewed following 12 months of implementation.</p>