

DRUG TYPE OR USE	PURPOSE	PBAC OUTCOME
<p>Removing (delisting) over the counter (OTC) medicines from the PBS</p>	<p>The Minister (delegate) requested the PBAC provide advice on the following matter(s) under section 101(3) of <i>the National Health Act, 1953</i> (the Act).</p> <p>To review the drugs listed on the PBS which are also available for over the counter (OTC) purchase, and to advise which of those items may be appropriate to remove from the PBS, and what criteria for determining delisting should apply to future consideration of OTC medicines on the PBS.</p> <p>For any OTC product that the PBAC considered may be removed from the PBS, the PBAC was requested to provide advice to the Minister under s101(4AAB) of the <i>National Health Act 1953</i> (Act) in relation to the proposed revocation of the declaration that this is a drug to which Part VII of the Act applies.</p>	<p>The following principles were considered to be appropriate by the PBAC and were applied in identifying drugs to be proposed for delisting:</p> <ul style="list-style-type: none"> • Schedule 2 or 3 OTC medicine; • Low ex-manufacturer price, where access is unlikely to change appreciably in the absence of PBS subsidy; • Products unlikely to be highly reliant on specialist prescribing and management; • Products where the PBAC has previously considered that the evidence for the current arrangements for subsidy is not overwhelming (e.g. blood glucose test strips). <p>The following principles were considered to be appropriate by the PBAC and were applied in identifying drugs that may be considered for retention on the PBS:</p> <ul style="list-style-type: none"> • High ex-manufacturer price, likely to prevent access to patients in the absence of PBS subsidy; • Drugs for urgent or emergency situations, where the fewest possible barriers to access should be maintained; • Products that are considered OTC only because they are not Scheduled medicines, but are unlikely to be purchased OTC; • Drugs listed on the Palliative Care Schedule or with listings pertaining to Aboriginal or Torres Strait Islander patients. <p>The PBAC considered that these criteria should be used to assess future OTC submissions seeking PBS listing.</p> <p>The PBAC advised that the following categories of PBS listed OTC drugs were essential and should be retained on the PBS:</p> <ul style="list-style-type: none"> • Drugs for emergency situations - the PBAC considered that the importance of unhindered access to these products required their retention on the PBS <ul style="list-style-type: none"> ○ Adrenaline ○ Glucagon ○ Glyceryl Trinitrate ○ Isosorbide Dinitrate ○ Salbutamol ○ Theophylline

		<ul style="list-style-type: none"> ○ Terbutaline • Nicotine Replacement Therapy • Listings on the Palliative Care Schedule - where products listed in the Palliative Care Schedule also having a dual listing in the General Schedule, the PBAC recommended retaining only the Palliative Care listing • Nutritional products - these products are used to manage conditions such as tyrosinamia, glutaric aciduria type 1 and methylmalonic acidaemia. The PBAC noted that the ex-manufacturer price for these formulae can be in excess of \$3,000 for a one month supply, and considered that delisting would effectively make them unavailable for many Australian patients. • OTC listings for patients of Aboriginal or Torres Strait Islander (ATSI) background • PBS listed products intended for IV delivery: <ul style="list-style-type: none"> ○ Electrolyte replacement, solution ○ Glucose ○ Gelatin – succinylated ○ Hydroxyethyl starch 130/0.4 ○ Sodium chloride ○ Sodium chloride with glucose ○ Sodium lactate compound • Folic Acid 0.5mg – The PBAC recommended retaining folic acid 0.5mg as a Restricted Benefit listing for Aboriginal or Torres Strait Islander patients. <p><u>Recommendations to retain products on the PBS due to high cost</u></p> <p>The PBAC advised that where the ex-manufacturer price of an OTC product is over the PBS Concessional co-payment, it should remain on the PBS. The PBAC considered that this approach would retain access to products that, without PBS subsidy, would be unaffordable for many patients.</p> <p><u>Recommendations to delist OTC products from the PBS</u></p> <p>The PBAC recommended that products with an ex-manufacturer price below the PBS Concessional co-payment should be delisted from the PBS. The PBAC considered that access to these products would be unaffected by the removal of PBS subsidy.</p> <p>With regard to blood glucose test strips, although these products are priced above the PBS</p>
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