**Agenda Item 14.10**

**REMOVING (DELISTING) OVER THE COUNTER MEDICINES FROM THE PBS**

**1 Purpose of Item**

* 1. The Minister (delegate) requested that the PBAC provide advice on the following matter(s) under section 101(3) of *the National Health Act, 1953* (the Act):

To provide advice as to specific drugs that are listed on the PBS which are also available for over the counter (OTC) purchase, and to advise which of those items it may be appropriate to remove from the PBS.

For any OTC product that the PBAC considers may be removed from the PBS, the PBAC is requested to provide advice to the Minister under s101(4AAB) of the *National Health Act 1953* (Act) in relation to the proposed revocation of the declaration that this is a drug to which Part VII of the Act applies.

1. **Background**
   1. At the April 2015 special meeting, the PBAC considered principles to apply to identifying OTC drugs that could be de-listed from the PBS.
   2. The PBAC applied the following principles were applied in identifying drugs to be proposed for delisting:

* 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 may not be conclusive (e.g. blood glucose test strips).
  1. The PBAC applied the following principles in identifying drugs that may be considered for retention on the PBS:
* High ex-manufacturer price, likely to prevent access by 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.
  1. The PBAC advised that the following categories of PBS listed OTC drugs were essential and should be retained on the PBS:
  2. Drugs for emergency situations – The PBAC noted that some of these items would not be expensive for patients to purchase without subsidy. However, the PBAC considered that the importance of unhindered access to these products required their retention on the PBS:
  + Adrenaline
  + Glucagon
  + Glyceryl Trinitrate
  + Isosorbide Dinitrate
  + Salbutamol
  + Theophylline
  + Terbutaline
  1. Nicotine Replacement Therapy – NRT patches were added to the PBS in 2011 following a submission from of a consortium of not-for-profit organisations. The PBAC recalled that listing was recommended in the context of a public health priority area, noting that reduction of chronic disease caused by smoking is a key focus of the national health taskforce on prevention. The PBAC considered that removal of NRT from the PBS would be a retrograde step in addressing a public health need.
  2. Listings on the Palliative Care Schedule - the Palliative Care Schedule was created in 2011 to provide for patients with “…*an active, progressive, far-advanced disease for whom the prognosis is limited and the focus of care is the quality of life.”* Streamlined listings provide maximum quantities and repeats sufficient for up to 4 months' therapy in total, with consultation with a palliative care physician or service required to access increased repeats for continuing treatment. 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:
  + Benzydamine mouthwash (dual listing)
  + Bisacodyl suppositories, enemas and tablets (dual listings)
  + Glycerol suppositories (dual listings)
  + Ibuprofen tablets 400mg, 30 (dual listings)
  + Lactulose mixture (dual listings)
  + Macrogol and macrogol+sodium chloride+potassium chloride+bicarbonate liquid
  + Paracetamol suppositories (Palliative care only) and 665mg modified release tablets (dual listing)
  + Rhamnus frangula + sterculia (Normacol Plus®) granules (dual listing)
  + Sorbitol + citrate + lauryl sulfoacetate sodium enemas (Microlax®, Microlette®) (dual listings)
  1. Nutritional products - these products are used to manage conditions such as tyrosinaemia, 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 could effectively make them unavailable for many Australian patients.
  2. OTC listings for patients of Aboriginal or Torres Strait Islander (ATSI) background - the PBAC considered that retention of these products was essential to efforts to improve delivery of healthcare to ATSI patients:
  + NRT 21mg/24hour and 25mg/16hour patches
  + Ketoconazole cream and shampoo
  + Miconazole cream and solution
  + Nystatin cream
  + Terbinafine cream
  + Thiamine tablets
  + Magnesium asparate tablets
  1. PBS listed products intended for IV delivery – the PBAC considered that maintaining the availability of these products was essential, and considered it unlikely that patients would seek to obtain these products by OTC purchase should they be removed from the PBS:
* Electrolyte replacement, solution
* Glucose
* Gelatin – succinylated
* Hydroxyethyl starch 130/0.4
* Sodium chloride
* Sodium chloride with glucose
* Sodium lactate compound
  1. Folic Acid 0.5mg – The PBAC recommended retaining of folic acid 0.5mg as a Restricted Benefit listing for Aboriginal or Torres Strait Islander patients.

Recommendations to retain products on the PBS due to high cost

* 1. 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, may be unaffordable for many patients.

1. **PBAC discussion**
   1. The PBAC noted the products that had been identified for de-listing.

*A full list of products will be published at a later date, separate from the Public Summary Document.*

* 1. This list is based on OTC items that have an ex-manufacturer price below the 2015 concessional co-payment ($6.10) per pack. The list excludes categories of OTC products that the PBAC considered should be retained on the PBS.
  2. Affected sponsors were invited to provide input for the Committee’s consideration. Only seven affected sponsors elected to provide comment – Aspen Pharmacare, Johnson & Johnson, GlaxoSmithKline, Pharmacor, Petrus Pharmaceuticals, AFT Pharmaceuticals and Roche Diagnostics.

Measures for patients of Aboriginal or Torres Strait Islander background

* 1. The *Closing the Gap PBS Co-payment Measure* provides co-payment relief for eligible Aboriginal and Torres Strait Islanders living with, or at risk of, chronic disease. Eligible General (non-concessional) patients who present a Closing the Gap (CTG) prescription are charged the concessional rate, and concessional patients pay no co-payment.
  2. To address identified barriers in accessing the PBS, special arrangements were introduced in 1999 for the supply of PBS medicines to clients of eligible remote area Aboriginal Health Services (AHSs). Under the provisions of section 100 of the *National Health Act 1953*, clients of approved remote area AHSs are able to receive medicines from the AHS, without the need for a normal PBS prescription form, and without charge.
  3. Both the CTG measure and supplies from remote area AHSs require PBS listings to operate.

The Paraplegic and Quadriplegic (Paraquad) Programme

* 1. The Paraquad scheme operates under the *National Health (Paraplegic and Quadriplegic Program) Special Arrangement 2010 (PB 118 of 2010).* Supply under the ParaQuad programme relies on a product having a PBS listing.
  2. The PBAC noted the products currently available on the Paraquad programme.

*A full list of products will be published at a later date, separately from the Public Summary Document.*

* 1. Of the OTC products identified for possible removal from the PBS, bisacodyl suppositories and glycerol suppositories are also available through the Paraquad program.

1. **Consumer comments**
   1. The PBAC noted and welcomed input from the sponsors (7) and correspondence from organisations: Arthritis Australia, Australian Rheumatology Association, Haemophilia Foundation Australia and Australian Self-Medication Institute via the Consumer Comments facility on the PBS website.
   2. The PBAC noted the following points raised by sponsors in reply to the PBAC’s advice on delisting of OTC products:

* The need for a specific mechanism for Indigenous peoples to maintain access to these products;
* Chloramphenicol eye drops and eye ointment are predominantly for Concessional card holders, are used in Indigenous patients and removal from the PBS may increase utilisation of fluoroquinolones;
* Patients that use bisacodyl suppositories would include paraplegic and quadriplegic patients, those receiving long-term nursing care, those with terminal malignant neoplasia, those with anorectal congenital abnormalities and those with megacolon.
  1. With specific regard to the PBAC’s advice on the delisting of paracetamol 665mg tablets, the following points were raised to support its continued listing on the PBS:
* Continued patient affordability and inclusion in PBS Safety Net arrangements;
* Variation of prices for products in OTC market, and limited access to discount pharmacies for specific patients
* Quality Use of Medicines – utilisation moving to other drugs (NSAIDs, COX-2 inhibitors or other analgesics);
* Low cost to the PBS;
* Inclusion in local and international guidelines;
* The impact of osteoarthritis on patients’ quality of life;
* Doctor, pharmacist and patient group support;
* Pharmacy-only distribution as a Schedule 2 product;

1. **PBAC Outcome**
   1. The PBAC considered the list of products identified for delisting from the PBS. The PBAC considered that general subsidy for these products was no longer appropriate. The PBAC noted the arguments in favour of retaining these products on the PBS, in particular in support of paracetamol 665mg. The PBAC considered that since these products would remain available to Australian patients in the absence of PBS subsidy, these arguments were not sufficient to justify the required Commonwealth expenditure.
   2. The PBAC noted the issues raised by stakeholders regarding maintenance of access for Aboriginal or Torres Strait Islander peoples, and for paraplegic and quadriplegic patients who rely on current access arrangements.
   3. The PBAC recommended that rather than delisting these drugs from the PBS, it would be appropriate for the PBS listings to be amended to restrict access to patients on Aboriginal or Torres Strait Islander background. The PBAC noted that such amendments would maintain access via the Closing the Gap PBS Co-payment Measure and via Section 100 Aboriginal Health Services.
   4. With regard to bisacodyl suppositories and glycerol suppositories, the PBAC recommended that the PBS listings for these products be amended to provide access specifically for paraplegic and quadriplegic patients for supply under the Paraquad programme.
   5. The PBAC considered that these recommendations, in conjunction with the listings previously recommended for retention (including those for palliative care), would address the needs of the most vulnerable Australian patients.