

PROPOSED LISTING CHANGES FOR OTC ITEMS FROM 1 JANUARY 2016

NOTES

Implications for OTC items on the Pharmaceutical Benefits Scheme (PBS)

Proposed 1 January 2016 listing changes for over-the-counter (OTC) products will proceed as set out below if the Minister for Health makes the recommended legal determinations. The determinations for January 2016 listings will be made in December 2015 in accordance with usual procedures. The information below clarifies intended outcomes.

In some cases, the sponsor has elected to de-list their brand from the PBS as a result of this measure, which is also reflected below. Furthermore, some brand deletions will result in the whole item being deleted from the PBS [note (4)]. In the following cases, the deletions will result in all forms and brands of a drug being deleted from the PBS:

Aluminium Hydroxide with Magnesium Trisilicate and Magnesium Hydroxide
Chloramphenicol
Ferrous fumarate
Ferrous fumarate with folic acid

Implications for OTC Items on the Repatriation Schedule of Pharmaceutical Benefits (RSPB):

The Budget measure allowed for the Department of Veterans' Affairs' Repatriation Pharmaceutical Reference Committee (RPRC) to determine whether any of the OTC items proposed for delisting from the PBS should be transferred to the RSPB to meet specific requirements for the veteran community, taking into account clinical considerations. The RPRC considered submissions from pharmaceutical sponsors for possible transfer to the RSPB. Following recommendations from the RPRC, the Minister for Veterans' Affairs has agreed to the transfer of items to the RSPB as indicated in the table below. It is intended the RSPB items will provide access as an unrestricted benefit, with the following exceptions:

Hydroxocobalamin items will be available on the RSPB for pernicious anaemia and proven vitamin B12 deficiencies other than pernicious anaemia; prophylaxis post gastrectomy of anaemias associated with vitamin B12 deficiency.

One of the items for paracetamol 500 mg tablet will include treatment for chronic arthropathies.

The item for paracetamol 665 mg tablet (modified release) will be for treatment of persistent pain that must be associated with osteoarthritis.

Key to recommendations:

- (1) Item(s) to remain available on the PBS only for patients identifying as an Aboriginal or Torres Strait Islander person, as recommended by PBAC
- (2) Item(s) to retain existing indications on the PBS for treatment of paraplegic and quadriplegic patients, as recommended by PBAC
- (3) Item(s) to retain existing indications on the PBS for palliative care, as recommended by PBAC
- (4) Item(s) also to be deleted from the PBS, as a result of sponsor request for brand deletion
- (5) Item(s) for addition to the RSPB, as recommended by RPRC.

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DRUG	FORM	PBAC/RPRC RECOMMENDATIONS	BRAND(S) CURRENTLY LISTED	SPONSOR REQUESTED BRAND DELETION
Aluminium Hydroxide with Magnesium Hydroxide	Oral suspension 200 mg-200 mg per 5 mL, 500 mL	General Schedule PBS item to be amended (1)	Mylanta P	—
Aluminium Hydroxide with Magnesium Trisilicate and Magnesium Hydroxide	Oral suspension 250 mg-120 mg-120 mg per 5 mL, 500 mL	General Schedule PBS item to be amended (1)	Gastrogel	Gastrogel (4)
Alginate acid with calcium carbonate and sodium bicarbonate	Oral liquid containing alginate acid as sodium alginate 1 g, calcium carbonate 320 mg and sodium bicarbonate 534 mg in 20 mL, 500 mL	General Schedule PBS item to be amended (1)	Gaviscon P	—
Aspirin	Tablet 100 mg	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Astrix Mayne Pharma Aspirin Spreen 100	Astrix Mayne Pharma Aspirin
Aspirin	Tablet, dispersible, 300 mg	General Schedule PBS items to be amended (1)	Solprin	—
Bisacodyl	Suppositories 10 mg, 10	General Schedule PBS item to be amended (1,2,3). Palliative Care Schedule items to remain unchanged. Access through the s100 <i>Paraplegic and Quadriplegic Program</i> to remain unchanged. New item to be added to RSPB (5)	Dulcolax Petrus Bisacodyl Suppositories	—
Bisacodyl	Suppositories 10 mg, 12	General Schedule PBS item to be amended (1,2,3). Palliative Care Schedule items to remain unchanged. Access through the s100 <i>Paraplegic and Quadriplegic Program</i> to remain unchanged. New item to be added to RSPB (5).	Petrus Bisacodyl Suppositories	—
Chloramphenicol	Eye drops 5 mg per mL, 10 mL	General Schedule PBS items to be amended (1)	Chlorsig	Chlorsig (4)
Chloramphenicol	Eye ointment 10 mg per g, 4 g	General Schedule PBS items to be amended (1)	Chlorsig	Chlorsig (4)
Electrolyte Replacement, Oral	Oral rehydration salts containing glucose 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	O.R.S. Repalyte New Formulation restore O.R.S.	O.R.S.
Ferrous fumarate	Tablet 200 mg (equivalent to 65.7 mg iron)	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Ferro-tab	Ferro-tab (4)
Ferrous Fumarate with Folic Acid	Tablet 310 mg (equivalent to 100 mg iron)-350 micrograms	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Ferro-f-tab	Ferro-f-tab (4)

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Folic Acid	Tablet 5 mg	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Megafof 5	—
Folic Acid	Tablet 500 micrograms	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Megafof 0.5 Foltabs 500	—
Glucose and Ketone Indicator—Urine	Test strips, 50 (Keto-Diabur-Test 5000)	General Schedule PBS items to be amended (1)	Keto-Diabur-Test 5000	—
Glucose and Ketone Indicator—Urine	Test strips, 50 (Keto-Diastix)	General Schedule PBS items to be amended (1)	Keto-Diastix	—
Glucose Indicator—Urine	Test strips, 50 (Diastix)	General Schedule PBS items to be amended (1)	Diastix	—
Glycerol	Suppositories 700 mg, 12	Palliative Care Schedule items to remain unchanged. General Schedule PBS item to be amended (1,2,3) Access through the s100 <i>Paraplegic and Quadriplegic Program</i> to remain unchanged. New item to be added to RSPB (5)	Petrus Pharmaceuticals Pty Ltd	—
Glycerol	Suppositories 1.4 g, 12	Palliative Care Schedule items to remain unchanged. General Schedule PBS item to be amended (1,2,3) Access through the s100 <i>Paraplegic and Quadriplegic Program</i> to remain unchanged. New item to be added to RSPB (5)	Petrus Pharmaceuticals Pty Ltd	—
Glycerol	Suppositories 2.8 g, 12	Palliative Care Schedule items to remain unchanged. General Schedule PBS item to be amended (1,2,3). Access through the s100 <i>Paraplegic and Quadriplegic Program</i> to remain unchanged. New item to be added to RSPB (5)	Petrus Pharmaceuticals Pty Ltd	—
Hydrocortisone	Cream containing hydrocortisone acetate 10 mg per g, 30 g	General Schedule PBS items to be amended (1)	Cortic-DS 1% Sigmacort	Cortic-DS 1% (4) Sigmacort (4)
Hydrocortisone	Ointment containing hydrocortisone acetate 10 mg per g, 30 g	General Schedule PBS items to be amended (1)	Cortic-DS 1% Sigmacort	Cortic-DS 1% (4) Sigmacort (4)
Hydroxocobalamin	Injection 1 mg (as acetate) in 1 mL	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Vita-B12	—
Hydroxocobalamin	Injection 1 mg (as chloride) in 1 mL	General Schedule PBS item to be amended (1) New item to be added to RSPB (5)	Hydroxo-B12 Neo-B12	Hydroxo-B12
Nystatin	Oral suspension 100,000 units per mL, 24 mL	General Schedule PBS item to be amended (1)	Mycostatin Nilstat	Mycostatin (4) Nilstat (4)

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Paracetamol	Tablet 500 mg	General Schedule PBS items to be amended (1) New item to be added to RSPB (5)	APO-Paracetamol Febridol Generic Health Pty Ltd Panamax Paracetamol (Sandoz) Paralgin Parapane	—
Paracetamol	Tablet 665 mg (modified release)	Palliative Care Schedule items to remain unchanged General Schedule PBS item to be amended (1) New items to be added to RSPB (5)	Osteomol 665 Paracetamol Panadol Osteo	Panadol Osteo
Paracetamol	Oral liquid 120 mg per 5 mL, 100 mL	General Schedule PBS items to be amended (1)	Panamax	—
Paracetamol	Oral liquid 240 mg per 5 mL, 200 mL	General Schedule PBS items to be amended (1) New item to be added to RPSB (5)	Panamax 240 Elixir	—