**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 once the Departmental delegate 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.

| **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) |
| Alginic acid with calcium carbonate and sodium bicarbonate | Oral liquid containing alginic 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  Spren 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 *Paraplegic and Quadriplegic Program* 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 *Paraplegic and Quadriplegic Program* 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) |
| Folic Acid | Tablet 5 mg | General Schedule PBS item to be amended (1)  New item to be added to RSPB (5) | Megafol 5 | — |
| Folic Acid | Tablet 500 micrograms | General Schedule PBS item to be amended (1)  New item to be added to RSPB (5) | Megafol 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 *Paraplegic and Quadriplegic Program* 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 *Paraplegic and Quadriplegic Program* 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 *Paraplegic and Quadriplegic Program* 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) |
| 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 | — |