

PB 1 of 2013

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013
(No. 1)1

*National Health Act 1953*

I, FELICITY McNEILL, First Assistant Secretary, Pharmaceutical Benefits Division, Department of Health and Ageing, delegate of the Minister for Health, make this Instrument under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953*.

Dated 8 January 2013

**FELICITY McNEILL**

First Assistant Secretary

Pharmaceutical Benefits Division

Department of Health and Ageing

1 Name of Instrument

 (1) This Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 1)*.

 (2) This Instrument may also be cited as PB 1 of 2013.

2 Commencement

This Instrument commences on 1 February 2013.

3 Amendment of *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)

 Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

Schedule 1 Amendments

1. Schedule 1, column headed “Determined Quantity”

*omit values in all instances where displayed in the column headed “Determined Quantity” for all Listed Drugs, except for:*

**Methoxyflurane**

*which retains the value “1” in the column headed “Determined Quantity”*

1. Schedule 1, entry for Alendronic Acid in the form Tablet 70 mg (as alendronate sodium)

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Fonat | AL | MP NP | C4122 C4123 C4133 |  | 4 | 5 | 4 |   |  |

1. Schedule 1, entry for Atenolol in the form Tablet 50 mg

omit from the column headed “Brand”: **Atenolol generichealth** substitute: **Atenolol GH**

1. Schedule 1, entry for Clopidogrel in the form Tablet 75 mg (as hydrogen sulfate)

omit from the column headed “Responsible Person” for the brand “Iscover”: **BQ** substitute: **AV**

1. Schedule 1, entry for Clopidogrel with aspirin in the form Tablet 75 mg (as hydrogen sulfate)-100 mg

omit from the column headed “Responsible Person” for the brand “DuoCover”: **BQ** substitute: **AV**

1. Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg *[Max Quantity 20; Number of Repeats 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Cyproterone Sandoz | HX | MP | C1014 C1230 C1404 | P1230 | 20 | 5 | 20 |  |  |

1. Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg *[Max Quantity 100; Number of Repeats 5]*

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Cyproterone Sandoz | HX | MP | C1014 C1230 C1404 | P1014 P1404 | 100 | 5 | 50 |   |  |

1. Schedule 1, entry for Exemestane

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Exemestane-GA | GM | MP NP | C1541 C2457 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Fludarabine in the form Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | AS-Fludarabine  | YA | MP | C3887 |  | See Note 3 | See Note 3 | 5 |  | PB(100) |

1. Schedule 1, entry for Gabapentin in each of the forms: Capsule 100 mg; Capsule 300 mg; Capsule 400 mg; and Tablet 800 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Gabapentin Pfizer | FZ | MP NP | C2664 |  | 100 | 5 | 100 |   |  |

1. Schedule 1, entry for Gemcitabine in each of the forms: Powder for I.V. infusion 200 mg (as hydrochloride); Powder for I.V. infusion 1 g (as hydrochloride); and Powder for I.V. infusion 2 g (as hydrochloride)

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | AS-Gemcitabine  | YA | MP |  |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Irbesartan in each of the forms: Tablet 75 mg; Tablet 150 mg; and Tablet 300 mg

omit from the column headed “Responsible Person” for the brand “Avapro”: **BQ** substitute: **AV**

1. Schedule 1, entry for Irbesartan with Hydrochlorothiazide in the form Tablet 150 mg-12.5 mg

omit from the column headed “Responsible Person” for the brand “Avapro HCT 150/12.5”: **BQ** substitute: **AV**

1. Schedule 1, entry for Irbesartan with Hydrochlorothiazide in the form Tablet 300 mg-12.5 mg

omit from the column headed “Responsible Person” for the brand “Avapro HCT 300/12.5”: **BQ** substitute: **AV**

1. Schedule 1, entry for Irbesartan with Hydrochlorothiazide in the form Tablet 300 mg-25 mg

omit from the column headed “Responsible Person” for the brand “Avapro HCT 300/25”: **BQ** substitute: **AV**

1. Schedule 1, entry for Lercanidipine in each of the forms: Tablet containing lercanidipine hydrochloride 10 mg; and Tablet containing lercanidipine hydrochloride 20 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Ledip | RA | MP NP |  |  | 28 | 5 | 28 |   |  |

1. Schedule 1, entry for Letrozole

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pharmacy Choice Letrozole  | RI | MP NP | C1608 C2691 C2692 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Lisinopril in the form Tablet 5 mg

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Prinivil 5 | MK | MP NP |  |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Metronidazole

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | I.V. infusion 500 mg in 100 mL | Injection | Baxter Healthcare Pty Ltd | BX | MP NP | C1300 C1448  |  | 10 | 0 | 10 |   |  |
|  |  |  |  |  | PDP | 1448  |  | 10 | 0 | 10 |   |  |
|  |  |  | DBL Metronidazole Intravenous Infusion | HH | MP NP | C1300 C1448 |  | 10 | 0 | 10 |   |  |
|  |  |  |  |  | PDP | 1448 |  | 10 | 0 | 10 |   |  |

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | I.V. infusion 500 mg in 100 mL | Injection | Baxter Healthcare Pty Ltd | BX | MP NP | C4167 C4168 C4169  |  | 10 | 0 | 1 |   |  |
|  |  |  |  |  | PDP | C4169 |  | 10 | 0 | 1 |   |  |
|  |  |  | DBL Metronidazole Intravenous Infusion | HH | MP NP | C4167 C4168 C4169  |  | 10 | 0 | 10 |   |  |
|  |  |  |  |  | PDP | C4169 |  | 10 | 0 | 10 |   |  |
|  |  |  | Metronidazole-Claris | AE | MP NP | C4167 C4168 C4169  |  | 10 | 0 | 5 |   |  |
|  |  |  |  |  | PDP | C4169 |  | 10 | 0 | 5 |   |  |

1. Schedule 1, entry for Nebivolol

omit from the column headed “Responsible Person” (all instances): **CS** substitute: **FK**

1. Schedule 1, entry for Oxaliplatin in each of the forms: Solution concentrate for I.V. infusion 50 mg in 10 mL; Solution concentrate for I.V. infusion 100 mg in 20 mL; and Solution concentrate for I.V. infusion 200 mg in 40 mL

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | AS-Oxaliplatin | YA | MP | C3900 C3901 C3930 C3939 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Oxybutynin in the form Transdermal patches 36 mg, 8

omit from the column headed “Responsible Person”:  **HH** substitute: **GM**

1. Schedule 1, entry for Paclitaxel in each of the forms: Solution concentrate for I.V. infusion 30 mg in 5 mL; Solution concentrate for I.V. infusion 100 mg in 16.7 mL; and Solution concentrate for I.V. infusion 300 mg in 50 mL

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | GN-Paclitaxel | YA | MP | C3186 C3890 C3902 C3917 C3955 C3956 |  | See Note 3 | See Note 3 | 1 |  | D(100) |

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 10 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pravastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |  |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 10 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pravastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 20 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pravastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |   |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 20 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pravastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pravastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |   |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pravastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 10 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |   |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 10 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 20 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |   |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 20 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 40 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |   |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 40 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 80 mg *[Max Quantity 30; Number of Repeats 5]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P1540 | 30 | 5 | 30 |   |  |
|  |  |  |  |  | NP | C1540 |  | 30 | 5 | 30 |   |  |

1. Schedule 1, entry for Simvastatin in the form Tablet 80 mg *[Max Quantity 30; Number of Repeats 11]*

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Simvastatin Winthrop | WA | MP | C1540 C3047 | P3047 | 30 | 11 | 30 |   |  |

1. Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) *for the following brands only*:

**APO-Sumatriptan; Chem mart Sumatriptan; Imigran; Sumagran 50; Sumagran Aspen 50; Sumatab;
and Terry White Chemists Sumatriptan**

omit from the column headed “Pack Quantity”: **4** substitute: **2**

1. Schedule 1, entry for Testosterone in each of the forms: Transdermal patches 12.2 mg, 60; and Transdermal patches 24.3 mg, 30

omit from the column headed “Responsible Person”:  **HH** substitute: **GM**

1. Schedule 1, entry for Topotecan

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Topotecan Agila | YA | MP | C3186 |  | See Note 3 | See Note 3 | 5 |  | D(100) |

1. Schedule 1, entry for Tramadol in each of the forms: Tablet (sustained release) containing tramadol hydrochloride 100 mg; Tablet (sustained release) containing tramadol hydrochloride 150 mg; and Tablet (sustained release) containing tramadol hydrochloride 200 mg

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Tramadol SR generichealth | GQ | MP NP | C1537 |  | 20 | 0 | 20 |  |  |

1. Schedule 1, entry for Tramadol in the form Injection containing tramadol hydrochloride 100 mg in 2 mL

omit from the column headed “Brand”: **Tramahexal** substitute: **Tramadol Sandoz**

1. Schedule 1, entry for Vinorelbine in each of the forms: Solution for I.V. infusion 10 mg (as tartrate) in 1 mL; and Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | AS-Vinorelbine | YA | MP | C3890 C3907 |  | See Note 3 | See Note 3 | 1 |  | PB(100) |

1. Schedule 3, details relevant to Responsible person code FK

omit: **Invida Australia Pty Ltd** substitute: **A.Menarini Australia Pty Ltd**

1. Schedule 3, after details relevant to Responsible person code XM

insert:

|  |  |  |
| --- | --- | --- |
| YA | Agila Australasia Pty Ltd |  12 154 055 339 |

1. Schedule 4, Part 1, entry for Metronidazole

substitute:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Metronidazole |  | P1416 |  | Treatment of anaerobic infections |  |
|  | C4167 |  |  | Acute anaerobic sepsisMust be treated in a hospital |  |
|  | C4168 |  |  | Prophylaxis to prevent infectionPatient must be undergoing large bowel surgery |  |
|  | C4169 |  |  | Acute anaerobic sepsisMust be treated in a hospital  |  |

**1Note**

All legislative instruments and compilations are registered on the Federal Register of Legislative Instruments kept under the *Legislative Instruments Act 2003.*

See <http://www.comlaw.gov.au>