

**PB 52 of 2018**

**National Health (Pharmaceutical Benefits – early supply) Amendment Instrument 2018 (No. 6)**

*National Health Act 1953*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I, LISA LA RANCE, Assistant Secretary, Pricing and PBS Policy Branch, Technology Assessment and Access Division, Department of Health, delegate of the Minister for Health, make this Instrument under subsection 84AAA(2) of the *National Health Act 1953*.

Dated 27th June 2018

**LISA LA RANCE**

Assistant Secretary

Pricing and PBS Policy Branch

Technology Assessment and Access Division

Department of Health

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. **Name of Instrument**
2. This Instrument is the *National Health (Pharmaceutical Benefits – early supply) Amendment Instrument 2018 (No. 6)*.
3. This Instrument may also be cited as PB 52 of 2018.
4. **Commencement**

This Instrument commences on 1 July 2018.

1. **Amendment of *National Health (Pharmaceutical Benefits—early supply) Instrument 2015* (PB 120 of 2015)**

Schedule 1 amends the *National Health (Pharmaceutical Benefits—early supply) Instrument 2015* (PB 120 of 2015).

**Schedule 1 Amendments**

1. **Schedule 1, entry for Aclidinium with eformoterol**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Aclidinium with formoterol | Powder for oral inhalation in breath actuated device containing aclidinium 340 micrograms (as bromide) with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | 20 | 1 | 5 |  |

1. **Schedule 1, entry for Amlodipine (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Amlodipine | Tablet 5 mg (as besilate) | 20 | 30 | 5 |  |
| Amlodipine | Tablet 10 mg (as besilate) | 20 | 30 | 5 |  |

1. **Schedule 1, entry for Amlodipine with atorvastatin (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Amlodipine with atorvastatin | Tablet 5 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 5 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 5 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 5 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 10 mg amlodipine (as besilate) with 10 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 10 mg amlodipine (as besilate) with 20 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 10 mg amlodipine (as besilate) with 40 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |
| Amlodipine with atorvastatin | Tablet 10 mg amlodipine (as besilate) with 80 mg atorvastatin (as calcium) | 20 | 30 | 5 |  |

1. **Schedule 1, entry for Amlodipine with valsartan (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Amlodipine with valsartan | Tablet 5 mg (as besilate)‑80 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan | Tablet 5 mg (as besilate)‑160 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan | Tablet 5 mg (as besilate)‑320 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan | Tablet 10 mg (as besilate)‑160 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan | Tablet 10 mg (as besilate)‑320 mg | 20 | 28 | 5 |  |

1. **Schedule 1, entry for Amlodipine with valsartan and hydrochlorothiazide (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 5 mg (as besilate)‑160 mg‑12.5 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 5 mg (as besilate)‑160 mg‑25 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 10 mg (as besilate)‑160 mg‑12.5 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 10 mg (as besilate)‑160 mg‑25 mg | 20 | 28 | 5 |  |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 10 mg (as besilate)‑320 mg‑25 mg | 20 | 28 | 5 |  |

1. **Schedule 1, entry for Balsalazide**

*omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Balsalazide | Capsule containing balsalazide sodium 750 mg | 20 | 180 | 5 |  |

1. **Schedule 1, omit entry for Benzhexol (all forms)**
2. **Schedule 1, after entry for Cabozantinib in the form Tablet 60 mg *[Maximum Quantity: 30; Number of Repeats: 5]***

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Calcitonin salmon | Injection 100 I.U. in 1 mL | 20 | 15 | 5 |  |

1. **Schedule 1, entry for Clopidogrel**

*omit:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Clopidogrel | Tablet 75 mg | 20 | 28 | 5 |  |

1. **Schedule 1, entry for Eprosartan (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Eprosartan | Tablet 400 mg (as mesilate) | 20 | 56 | 5 |  |
| Eprosartan | Tablet 600 mg (as mesilate) | 20 | 28 | 5 |  |

1. **Schedule 1, entry for Eprosartan with hydrochlorothiazide**

*omit from the column headed “Form”:* Tablet 600 mg eprosartan (as mesylate) with 12.5 mg hydrochlorothiazide

*substitute:* Tablet 600 mg eprosartan (as mesilate) with 12.5 mg hydrochlorothiazide

1. **Schedule 1, entry for Esomeprazole and clarithromycin and amoxycillin (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Esomeprazole and clarithromycin and amoxicillin | Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) | 20 | 1 | 0 |  |
| Esomeprazole and clarithromycin and amoxicillin | Pack containing 14 tablets (enteric coated) containing esomeprazole 20 mg (as magnesium trihydrate), 14 tablets clarithromycin 500 mg and 28 capsules amoxicillin 500 mg (as trihydrate) | 20 | 1 | 0 |  |

1. **Schedule 1, after entry for Esomeprazole and clarithromycin and amoxicillin (all forms)**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Estradiol | Tablet containing estradiol valerate 1 mg | 20 | 56 | 2 |  |
| Estradiol | Tablet containing estradiol valerate 2 mg | 20 | 56 | 2 |  |
| Estradiol | Tablet 2 mg | 20 | 56 | 2 |  |
| Estradiol | Transdermal gel 1 mg (as hemihydrate) in 1 g sachet, 28 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 390 micrograms, 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 585 micrograms, 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 750 micrograms (as hemihydrate), 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 780 micrograms, 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 1.17 mg, 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 1.5 mg (as hemihydrate), 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 1.56 mg, 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 2 mg, 4 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 3 mg (as hemihydrate), 8 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 3.8 mg, 4 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 5.7 mg, 4 | 20 | 1 | 5 |  |
| Estradiol | Transdermal patches 7.6 mg, 4 | 20 | 1 | 5 |  |
| Estradiol and estradiol with dydrogesterone | Pack containing 14 tablets estradiol 1 mg and 14 tablets estradiol 1 mg with dydrogesterone 10 mg | 20 | 1 | 5 |  |
| Estradiol and estradiol with dydrogesterone | Pack containing 14 tablets estradiol 2 mg and 14 tablets estradiol 2 mg with dydrogesterone 10 mg | 20 | 1 | 5 |  |
| Estradiol and estradiol with norethisterone | Pack containing 4 transdermal patches 780 micrograms estradiol (as hemihydrate) and 4 transdermal patches 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate | 20 | 1 | 5 |  |
| Estradiol and estradiol with norethisterone | Pack containing 4 transdermal patches 780 micrograms estradiol (as hemihydrate) and 4 transdermal patches 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate | 20 | 1 | 5 |  |
| Estradiol with dydrogesterone | Tablet 1 mg-5 mg | 20 | 28 | 5 |  |
| Estradiol with norethisterone | Transdermal patches containing 510 micrograms estradiol (as hemihydrate) with 4.8 mg norethisterone acetate, 8 | 20 | 1 | 5 |  |
| Estradiol with norethisterone | Transdermal patches containing 620 micrograms estradiol (as hemihydrate) with 2.7 mg norethisterone acetate, 8 | 20 | 1 | 5 |  |

1. **Schedule 1, entry for Frusemide**

*omit from the column headed “Listed drug” (all forms):* **Frusemide** *substitute:* **Furosemide**

1. **Schedule 1, entry for Levonorgestrel with ethinyloestradiol**

*omit from the column headed “Listed drug” (all forms):* **Levonorgestrel with ethinyloestradiol** *substitute:* **Levonorgestrel with ethinylestradiol**

1. **Schedule 1, after entry for Levonorgestrel with ethinylestradiol (all forms)**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Levothyroxine | Tablet containing 50 micrograms anhydrous levothyroxine sodium | 20 | 200 | 1 |  |
| Levothyroxine | Tablet containing 75 micrograms anhydrous levothyroxine sodium | 20 | 200 | 1 |  |
| Levothyroxine | Tablet containing 100 micrograms anhydrous levothyroxine sodium | 20 | 200 | 1 |  |
| Levothyroxine | Tablet containing 200 micrograms anhydrous levothyroxine sodium | 20 | 200 | 1 |  |

1. **Schedule 1, entry for Norethisterone with ethinyloestradiol**

*omit from the column headed “Listed drug” (all forms):* **Norethisterone with ethinyloestradiol** *substitute:* **Norethisterone with ethinylestradiol**

1. **Schedule 1, omit entry for Oestradiol (all forms)**
2. **Schedule 1, omit entry for Oestradiol and oestradiol with dydrogesterone (all forms)**
3. **Schedule 1, omit entry for Oestradiol and oestradiol with norethisterone (all forms)**
4. **Schedule 1, omit entry for Oestradiol with dydrogesterone**
5. **Schedule 1, omit entry for Oestradiol with norethisterone (all forms)**
6. **Schedule 1, entry for Olmesartan with amlodipine (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) | 20 | 30 | 5 |  |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) | 20 | 30 | 5 |  |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) | 20 | 30 | 5 |  |

1. **Schedule 1, entry for Perindopril with amlodipine (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Perindopril with amlodipine | Tablet containing 5 mg perindopril arginine with 5 mg amlodipine (as besilate) | 20 | 30 | 5 |  |
| Perindopril with amlodipine | Tablet containing 5 mg perindopril arginine with 10 mg amlodipine (as besilate) | 20 | 30 | 5 |  |
| Perindopril with amlodipine | Tablet containing 10 mg perindopril arginine with 5 mg amlodipine (as besilate) | 20 | 30 | 5 |  |
| Perindopril with amlodipine | Tablet containing 10 mg perindopril arginine with 10 mg amlodipine (as besilate) | 20 | 30 | 5 |  |

1. **Schedule 1, entry for Phenobarbitone**

*omit from the column headed “Listed drug”:* **Phenobarbitone** *substitute:* **Phenobarbital**

1. **Schedule 1, after entry for Ribavirin in the form Tablet 600 mg *[Maximum Quantity: 28; Number of Repeats: 5]***

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Ribociclib | Tablet 200 mg | 20 | 21 | 5 |  |
| Ribociclib | Tablet 200 mg | 20 | 42 | 5 |  |
| Ribociclib | Tablet 200 mg | 20 | 63 | 5 |  |

1. **Schedule 1, entry for Sorafenib**

*omit from the column headed “Form” (twice occurring):* Tablet 200 mg (as tosylate)

*substitute:* Tablet 200 mg (as tosilate)

1. **Schedule 1, entry for Telmisartan with amlodipine (all forms)**

*substitute:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Telmisartan with amlodipine | Tablet 40 mg‑5 mg (as besilate) | 20 | 28 | 5 |  |
| Telmisartan with amlodipine | Tablet 40 mg‑10 mg (as besilate) | 20 | 28 | 5 |  |
| Telmisartan with amlodipine | Tablet 80 mg‑5 mg (as besilate) | 20 | 28 | 5 |  |
| Telmisartan with amlodipine | Tablet 80 mg‑10 mg (as besilate) | 20 | 28 | 5 |  |

1. **Schedule 1, omit entry for Thyroxine (all forms)**
2. **Schedule 1, after entry for Triamcinolone**

*insert:*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Trihexyphenidyl | Tablet containing trihexyphenidyl hydrochloride 2 mg | 20 | 200 | 2 |  |
| Trihexyphenidyl | Tablet containing trihexyphenidyl hydrochloride 5 mg | 20 | 200 | 1 |  |