

PB 61 of 2013

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013   
(No. 11)

*National Health Act 1953*

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

Dated 6 September 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. 11)*.

(2) This Instrument may also be cited as PB 61 of 2013.

2 Commencement

This Instrument commences on 1 October 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, entry for Aciclovir in the form Tablet 200 mg

omit from the column headed “Responsible Person” for the brand “Lovir” (twice occurring): **GM** substitute: **GN**

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

omit from the column headed “Responsible Person” for the brand “Alendronate-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Alendronic acid with colecalciferol in the form Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol

omit from the column headed “Responsible Person” for the brand “Dronalen Plus”: **GM** substitute: **GN**

1. Schedule 1, entry for Alprazolam in each of the forms: Tablet 1 mg; and Tablet 2 mg

omit from the column headed “Responsible Person” for the brand “Ralozam”: **GM** substitute: **GN**

1. Schedule 1, entry for Amlodipine in each of the forms: Tablet 5 mg (as besylate); and Tablet 10 mg (as besylate)

omit from the column headed “Responsible Person” for the brand “Amlodipine-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Amoxycillin in each of the forms: Capsule 250 mg (as trihydrate); and Capsule 500 mg (as trihydrate)

omit from the column headed “Responsible Person” for the brand “Amoxycillin-GA” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Amoxycillin in each of the forms: Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL; and Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL

omit from the column headed “Responsible Person” for the brand “Bgramin” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

omit from the column headed “Responsible Person” for the brand “GA-Amclav 500/125” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate)

omit from the column headed “Responsible Person” for the brand “GA-Amclav Forte 875/125” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Powder for oral suspension containing 125 mg amoxycillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL

omit from the column headed “Responsible Person” for the brand “GA-Amclav 125/31.25” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Amoxycillin with Clavulanic Acid in the form Powder for oral suspension containing 400 mg amoxycillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL

omit from the column headed “Responsible Person” for the brand “GA-Amclav Forte 400/57” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Ampicillin in each of the forms: Powder for injection 500 mg (as sodium); and Powder for injection 1 g (as sodium)

omit from the column headed “Responsible Person” for the brand “Ibimicyn” (all instances): **WQ** substitute: **GN**

1. Schedule 1, entry for Anastrozole in the form Tablet 1 mg
   * 1. omit from the column headed “Responsible Person” for the brand “Anastrozole-GA”: **GM** substitute: **GN**
     2. omit from the column headed “Responsible Person” for the brand “Anzole”: **WQ** substitute: **UA**
2. Schedule 1, entry for Atorvastatin in each of the forms: Tablet 10 mg (as calcium); Tablet 20 mg (as calcium); Tablet 40 mg (as calcium); Tablet 80 mg (as calcium)

omit from the column headed “Responsible Person” for the brand “Atorvachol” (all instances): **GM** substitute: **GN**

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

omit from the column headed “Responsible Person” for the brand “Azamun”: **GM** substitute: **GN**

1. Schedule 1, entry for Azithromycin in the form Tablet 500 mg (as dihydrate)

omit from the column headed “Responsible Person”for the brand “Zitrocin” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Bicalutamide

omit from the column headed “Responsible Person” for the brand “Bicalutamide-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 2.5 mg

omit from the column headed “Responsible Person” for the brand “Biso 2.5”: **WQ** substitute: **GN**

1. Schedule 1, entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 5 mg

omit from the column headed “Responsible Person” for the brand “Biso 5”: **WQ** substitute: **GN**

1. Schedule 1, entry for Bisoprolol in the form Tablet containing bisoprolol fumarate 10 mg

omit from the column headed “Responsible Person” for the brand “Biso 10”: **WQ** substitute: **GN**

1. Schedule 1, entry for Bleomycin in the form Powder for injection containing bleomycin sulfate 15,000 I.U

omit from the column headed “Responsible Person” for the brand “Bleo 15K”: **WQ** substitute: **GN**

1. Schedule 1, entry for Boceprevir in the form Capsule 200 mg
   * 1. omit from the column headed “Maximum Quantity”: **See Note 3** substitute: **336**
     2. omit from the column headed “Number of Repeats”:  **See Note 3** substitute: **10**
2. Schedule 1, entry for Bupropion

*omit from the column headed “Responsible Person” for the brand “Prexaton” (twice occurring):* **GM** *substitute:* **GN**

1. Schedule 1, entry for Cabergoline in the form Tablet 500 micrograms

omit from the column headed “Responsible Person” for the brand “Dostan” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Cabergoline in each of the forms: Tablet 1 mg; and Tablet 2 mg

omit from the column headed “Responsible Person” for the brand “Cobasol”: **GM** substitute: **GN**

1. Schedule 1, entry for Calcitriol

omit from the column headed “Responsible Person” for the brand “Calcitriol-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 4 mg
2. omit from the column headed “Responsible Person” for the brand **“**Candesartan-GA”: **GM** substitute: **GN**
3. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan RBX | RA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 8 mg
   * 1. omit from the column headed “Responsible Person” for the brand **“**Candesartan-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan RBX | RA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 16 mg
   * 1. omit from the column headed “Responsible Person” for the brand **“**Candesartan-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan RBX | RA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan in the form Tablet containing candesartan cilexetil 32 mg
   * 1. omit from the column headed “Responsible Person” for the brand **“**Candesartan-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan RBX | RA | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg
   * 1. omit from the column headed “Responsible Person” for the brand **“**Candesartan HCTZ-GA 16/12.5”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan HCTZ RBX 16/12.5 | RA | MP NP | C3307 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg
2. omit from the column headed “Responsible Person” for the brand **“**Candesartan HCTZ-GA 32/12.5”: **GM** substitute: **GN**
3. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan HCTZ RBX 32/12.5 | RA | MP NP | C3307 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Candesartan with Hydrochlorothiazide in the form Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg
2. omit from the column headed “Responsible Person” for the brand **“**Candesartan HCTZ-GA 32/25”: **GM** substitute: **GN**
3. in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Candesartan HCTZ RBX 32/25 | RA | MP NP | C3307 |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Carbomer in the form Eye gel 2 mg per g, 10 g
2. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | GelTears | BU | MP | C1362 C3036 | P1362 | 1 | 5 | 1 |  |  |
|  |  |  |  |  | NP AO | C1362 |  | 1 | 5 | 1 |  |  |

1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | GelTears | BU | MP | C1362 C3036 | P3036 | 1 | 11 | 1 |  |  |

1. Schedule 1, entry for Carboplatin in each of the forms: Solution for I.V. injection 50 mg in 5 mL; Solution for I.V. injection 150 mg in   
   15 mL; and Solution for I.V. injection 450 mg in 45 mL

omit from the column headed “Responsible Person” for the brand “Carbaccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Carvedilol in each of the forms: Tablet 3.125 mg; Tablet 6.25 mg; Tablet 12.5 mg; and Tablet 25 mg

omit from the column headed “Responsible Person” for the brand “GN-Carvedilol”: **GM** substitute: **GN**

1. Schedule 1, entry for Cephalexin in each of the forms: Capsule 250 mg (anhydrous); Capsule 500 mg (anhydrous); Granules for oral suspension 125 mg per 5 mL, 100 mL; and Granules for oral suspension 250 mg per 5 mL, 100 mL

omit from the column headed “Responsible Person” for the brand “Cilex” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Cephazolin in the form Powder for injection 500 mg (as sodium)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Hospira Pty Limited | HH | MP NP | C1169 C1846  C1847 C3132 |  | 10 | 0 | 5 |  |  |

1. Schedule 1, entry for Ciprofloxacin in each of the forms: Tablet 500 mg (as hydrochloride); and Tablet 750 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Ciprofloxacin-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Citalopram in the form Tablet 20 mg (as hydrobromide)

omit from the column headed “Responsible Person” for the brand “Ciazil”: **GM** substitute: **UA**

1. Schedule 1, entry for Clarithromycin in the form Tablet 250 mg

omit from the column headed “Responsible Person” for the brand “Clarac”: **GM** substitute: **GN**

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

omit from the column headed “Responsible Person” for the brand “Clopidogrel-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Coal Tar – Prepared

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

1. Schedule 1, entry for Cromoglycic Acid in the form Capsule containing powder for oral inhalation containing sodium cromoglycate 20 mg (for use in Intal Spinhaler or Intal Halermatic)

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

1. Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 50 mg

omit from the column headed “Responsible Person” for the brand “Procur” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Cyproterone in the form Tablet containing cyproterone acetate 100 mg

omit from the column headed “Responsible Person” for the brand “Procur 100”: **GM** substitute: **GN**

1. Schedule 1, entry for Dabigatran etexilate in the form Capsule 110 mg (as mesilate)

omit from the column headed “Purposes” for the code “C4269”: **C** substitute: **P**

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

omit from the column headed “Responsible Person” for the brand “Diazepam-GA” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 25 mg *[Maximum Quantity 100; Number of Repeats 0]*

omit from the column headed “Responsible Person” for the brand “Diclofenac-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 25 mg *[Maximum Quantity 100; Number of Repeats 3]*
   * 1. *omit from the column headed “Responsible Person” for the brand “Diclofenac-GA” (first instance):* GM *substitute:* GN
     2. omit

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Diclofenac-GA | GM | MP NP | C1036 C1054 C3645 C3646 | P1036 P1054 P3645 | 100 | 3 | 50 |  |  |

* + 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Diclofenac Sandoz | SZ | MP NP | C1036 C1054 C3645 C3646 | P1036 P1054 P3645 | 100 | 3 | 50 |  |  |

1. Schedule 1, entry for Diclofenac in the form Tablet (enteric coated) containing diclofenac sodium 50 mg

omit from the column headed “Responsible Person” for the brand “Diclofenac-GA” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Diltiazem in the form Tablet containing diltiazem hydrochloride 60 mg

omit from the column headed “Responsible Person” for the brand “Dilzem 60 mg”: **GM** substitute: **GN**

1. Schedule 1, entry for Donepezil in each of the forms: Tablet containing donepezil hydrochloride 5 mg; and Tablet containing donepezil hydrochloride 10 mg

omit from the column headed “Responsible Person” for the brand “Donepezil-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Doxorubicin in the form Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial

omit from the column headed “Responsible Person” for the brand “Accord Doxorubicin”: **WQ** substitute: **GN**

1. Schedule 1, entry for Doxorubicin in the form Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial

omit from the column headed “Responsible Person” for the brand “Accord Doxorubicin”: **WQ** substitute: **GN**

1. Schedule 1, entry for Doxycycline in the form Tablet 50 mg (as hydrochloride)
   * 1. omit from the column headed “Responsible Person” for the brand “Doxy-50”: **GM** substitute: **GN**
     2. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Vibra-Tabs | PF | MP NP | C1346 C1851 C1852 |  | 25 | 5 | 25 |  |  |

1. Schedule 1, entry for Doxycycline in the form Tablet 100 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Doxy-100” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Duloxetine in each of the forms: Capsule 30 mg (as hydrochloride); and Capsule 60 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Drulox” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Electrolyte Replacement, Oral

omit from the column headed “Responsible Person” for the brand “restore O.R.S.”: **GM** substitute: **GN**

1. Schedule 1, entry for Enalapril in each of the forms: Tablet containing enalapril maleate 5 mg; Tablet containing enalapril maleate 10 mg; and Tablet containing enalapril maleate 20 mg

omit from the column headed “Responsible Person” for the brand “Enalapril-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Epirubicin in each of the forms: Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL; Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL; and Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL

omit from the column headed “Responsible Person” for the brand “Epiccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Epirubicin in the form Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL

omit from the column headed “Responsible Person” for the brand “Epiccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Escitalopram in each of the forms: Tablet 10 mg (as oxalate); and Tablet containing 20 mg (as oxalate)

omit from the column headed “Responsible Person” for the brand “Esipram”: **GM** substitute: **UA**

1. Schedule 1, entry for Exemestane

omit from the column headed “Responsible Person” for the brand “Exemestane-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Famciclovir in each of the forms: Tablet 125 mg; Tablet 250 mg; and Tablet 500 mg

omit from the column headed “Responsible Person” for the brand “Famciclovir-GA” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Famotidine in each of the forms: Tablet 20 mg; and Tablet 40 mg

omit from the column headed “Responsible Person” for the brand “Pepzan”: **GM** substitute: **GN**

1. Schedule 1, entry for Fentanyl in the form Transdermal patch 2.063 mg

omit from the column headed “Responsible Person” for the brand “Dutran 12”: **GM** substitute: **GN**

1. Schedule 1, entry for Fentanyl in the form Transdermal patch 4.125 mg

omit from the column headed “Responsible Person” for the brand “Dutran 25”: **GM** substitute: **GN**

1. Schedule 1, entry for Fentanyl in the form Transdermal patch 8.25 mg

omit from the column headed “Responsible Person” for the brand “Dutran 50”: **GM** substitute: **GN**

1. Schedule 1, entry for Fentanyl in the form Transdermal patch 12.375 mg

omit from the column headed “Responsible Person” for the brand “Dutran 75”: **GM** substitute: **GN**

1. Schedule 1, entry for Fentanyl in the form Transdermal patch 16.5 mg

omit from the column headed “Responsible Person” for the brand “Dutran 100”: **GM** substitute: **GN**

1. Schedule 1, entry for Flucloxacillin in each of the forms: Powder for injection 500 mg (as sodium); and Powder for injection 1 g (as sodium)

omit from the column headed “Responsible Person” for the brand “Flubiclox” (all instances): **WQ** substitute: **GN**

1. Schedule 1, entry for Fludarabine in the form Powder for I.V. injection containing fludarabine phosphate 50 mg

omit from the column headed “Responsible Person” for the brand “Farine”: **WQ** substitute: **GN**

1. Schedule 1, entry for Fluoxetine in the form Capsule 20 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Fluoxetine-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Fluvoxamine in each of the forms: Tablet containing fluvoxamine maleate 50 mg; and Tablet containing fluvoxamine maleate 100 mg

omit from the column headed “Responsible Person” for the brand “Fluvoxamine GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Fosinopril with Hydrochlorothiazide in the form Tablet containing fosinopril sodium 10 mg with hydrochlorothiazide 12.5 mg

omit from the column headed “Responsible Person” for the brand “Fosinopril/HCTZ‑GA 10/12.5”: **GM** substitute: **GN**

1. Schedule 1, entry for Fosinopril with Hydrochlorothiazide in the form Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg

omit from the column headed “Responsible Person” for the brand “Fosinopril/HCTZ‑GA 20/12.5”: **GM** substitute: **GN**

1. Schedule 1, entry for Frusemide in the form Tablet 20 mg

omit from the column headed “Responsible Person” for the brand “Frusid”: **GM** substitute: **GN**

1. Schedule 1, entry for Frusemide in the form Tablet 40 mg

omit from the column headed “Responsible Person” for the brand “Frusid”: **GM** substitute: **UA**

1. Schedule 1, entry for Gabapentin in the form Capsule 100 mg
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | DBL Gabapentin | HH | MP NP | C2664 |  | 100 | 5 | 100 |  |  |

* + 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Gabapentin Aspen 100 | FM | MP NP | C2664 |  | 100 | 5 | 100 |  |  |

1. Schedule 1, entry for Gabapentin in the form Capsule 300 mg
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | DBL Gabapentin | HH | MP NP | C2664 |  | 100 | 5 | 100 |  |  |

* + 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Gabapentin Aspen 300 | FM | MP NP | C2664 |  | 100 | 5 | 100 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Gabapentin-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Gabapentin in the form Capsule 400 mg
   * 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | DBL Gabapentin | HH | MP NP | C2664 |  | 100 | 5 | 100 |  |  |

* + 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Gabapentin Aspen 400 | FM | MP NP | C2664 |  | 100 | 5 | 100 |  |  |

1. Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 200 mg (as hydrochloride)
   * 1. omit:

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

* + 1. *omit from the column headed “Responsible Person” for the brand “Gemaccord”:* WQ *substitute:* GN
    2. *omit from the column headed “Responsible Person” for the brand “Gemcitabine Actavis”:* WQ *substitute:* GN
    3. *omit from the column headed “Responsible Person” for the brand “Gemplan”:* WQ *substitute:* GN

1. Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 1 g (as hydrochloride)
   * 1. omit:

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

* + 1. *omit from the column headed “Responsible Person” for the brand “Gemaccord”:* WQ *substitute:* GN
    2. *omit from the column headed “Responsible Person” for the brand “Gemcitabine Actavis”:* WQ *substitute:* GN
    3. *omit from the column headed “Responsible Person” for the brand “Gemplan”:* WQ *substitute:* GN

1. Schedule 1, entry for Gemcitabine in the form Powder for I.V. infusion 2 g (as hydrochloride)
   * 1. omit:

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

* + 1. *omit from the column headed “Responsible Person” for the brand “Gemcitabine Actavis 2000”:* WQ *substitute:* GN

1. Schedule 1, entry for Gemfibrozil in the form Tablet 600 mg

omit from the column headed “Responsible Person” for the brand “Gemfibrozil-GA” (twice occurring): **GM** substitute: **UA**

1. Schedule 1, entry for Glimepiride in the form Tablet 1 mg

omit from the column headed “Responsible Person” for the brand “Glimepiride GA 1”: **GM** substitute: **GN**

1. Schedule 1, entry for Glimepiride in the form Tablet 2 mg

omit from the column headed “Responsible Person” for the brand “Glimepiride GA 2”: **GM** substitute: **GN**

1. Schedule 1, entry for Glimepiride in the form Tablet 3 mg

omit from the column headed “Responsible Person” for the brand “Glimepiride GA 3”: **GM** substitute: **GN**

1. Schedule 1, entry for Glimepiride in the form Tablet 4 mg

omit from the column headed “Responsible Person” for the brand “Glimepiride GA 4”: **GM** substitute: **GN**

1. Schedule 1, entry for Hydroxychloroquine

omit from the column headed “Responsible Person” for the brand “Hydroxychloroquine Actavis”: **GM** substitute: **GN**

1. Schedule 1, entry for Indapamide in the form Tablet containing indapamide hemihydrate 2.5 mg

omit from the column headed “Responsible Person” for the brand “Indapamide-GA”: **GM** substitute: **GN**

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 “Irbesartan-GA”: **GM** substitute: **GN**

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 “Irbesartan HCTZ-GA 150/12.5”: **GM** substitute: **GN**

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 “Irbesartan HCTZ-GA 300/12.5”: **GM** substitute: **GN**

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 “Irbesartan HCTZ-GA 300/25”: **GM** substitute: **GN**

1. Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL
   * 1. *omit from the column headed “Responsible Person” for the brand “Irinoccord”:* WQ *substitute:* GN
     2. *omit from the column headed “Responsible Person” for the brand “Tecan”:* WQ *substitute:* GN
2. Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL
   * 1. *omit from the column headed “Responsible Person” for the brand “Irinoccord”:* WQ *substitute:* GN
     2. *omit from the column headed “Responsible Person” for the brand “Tecan”:* WQ *substitute:* GN
3. Schedule 1, entry for Irinotecan in the form I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL

*omit from the column headed “Responsible Person” for the brand “Tecan”:* WQ *substitute:* GN

1. Schedule 1, entry for Isosorbide Mononitrate in the form Tablet 60 mg (sustained release)

omit from the column headed “Responsible Person” for the brand “Imtrate 60 mg”: **GM** substitute: **GN**

1. Schedule 1, entry for Isotretinoin in the form Capsule 10 mg
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Isotretinoin SCP 10 | CR | MP | C1354 |  | 60 | 3 | 60 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Oratane”: **GM** substitute: **GN**

1. Schedule 1, entry for Isotretinoin in the form Capsule 20 mg
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Isotretinoin SCP 20 | CR | MP | C1354 |  | 60 | 3 | 60 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Oratane”: **GM** substitute: **GN**

1. Schedule 1, entry for Isotretinoin in the form Capsule 40 mg

omit from the column headed “Responsible Person” for the brand “Oratane”: **GM** substitute: **GN**

1. Schedule 1, entry for Lactulose

omit from the column headed “Responsible Person” for the brand “Lac-Dol” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Leflunomide in each of the forms: Tablet 10 mg; and Tablet 20 mg

omit from the column headed “Responsible Person” for the brand “Leflunomide-GA”: **GM** substitute: **GN**

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

omit from the column headed “Responsible Person” for the brand “Lercadip”: **GM** substitute: **GN**

1. Schedule 1, entry for Letrozole
   * 1. omit from the column headed “Responsible Person” for the brand “Letrozole-GA”: **GM** substitute: **GN**
     2. omit from the column headed “Responsible Person” for the brand “Lezole”: **WQ** substitute: **UA**
2. Schedule 1, entry for Levetiracetam in each of the forms: Tablet 250 mg; Tablet 500 mg; and Tablet 1 g

omit from the column headed “Responsible Person” for the brand “Kepcet”: **GM** substitute: **GN**

1. Schedule 1, entry for Macrogol 3350 in the form Sachets containing powder for oral solution 13.125 g with electrolytes, 30

omit from the column headed “Responsible Person” for the brand “LaxaCon”: **GM** substitute: **GN**

1. Schedule 1, entry for Meloxicam in each of the forms: Tablet 7.5 mg; and Tablet 15 mg

omit from the column headed “Responsible Person” for the brand “Meloxicam-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Meloxicam in the form Capsule 7.5 mg
   * 1. omit from the column headed “Responsible Person” for the brand “Melox 7.5”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Meloxicam Sandoz | SZ | MP NP | C1547 C1848 |  | 30 | 3 | 30 |  |  |

1. Schedule 1, entry for Meloxicam in the form Capsule 15 mg
   * 1. omit from the column headed “Responsible Person” for the brand “Melox 15”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Meloxicam Sandoz | SZ | MP NP | C1547 C1848 |  | 30 | 3 | 30 |  |  |

1. Schedule 1, entry for Metformin in the form Tablet containing metformin hydrochloride 500 mg

omit from the column headed “Responsible Person” for the brand “Metformin-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Metformin in each of the forms: Tablet containing metformin hydrochloride 850 mg; and Tablet containing metformin hydrochloride 1 g

omit from the column headed “Responsible Person” for the brand “Metformin-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Methotrexate in the form Injection 50 mg in 2 mL vial

omit from the column headed “Responsible Person” for the brand “Methaccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Methotrexate in the form Solution concentrate for I.V. infusion 1000 mg in 10 mL vial

omit from the column headed “Responsible Person” for the brand “Methaccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Mirtazapine in the form Tablet 30 mg

omit from the column headed “Responsible Person” for the brand “Mirtazapine-DP”: **GM** substitute: **UA**

1. Schedule 1, entry for Mirtazapine in the form Tablet 45 mg

omit from the column headed “Responsible Person” for the brand “Mirtazapine-GA”: **GM** substitute: **GN**

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

omit from the column headed “Responsible Person” for the brand “Clobemix”: **GM** substitute: **GN**

1. Schedule 1, entry for Montelukast in the form Tablet, chewable, 4 mg (as sodium)
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Auro-Montelukast Tabs 4 | DO | MP NP | C2617 |  | 28 | 5 | 28 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Montair 4”: **GM** substitute: **GN**

1. Schedule 1, entry for Montelukast in the form Tablet, chewable, 5 mg (as sodium)
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Auro-Montelukast Tabs 5 | DO | MP NP | C2618 C3217 |  | 28 | 5 | 28 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Montair 5”: **GM** substitute: **GN**

1. Schedule 1, entry for Norfloxacin

omit from the column headed “Responsible Person” for the brand “Norfloxacin-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Olanzapine in each of the forms: Tablet 2.5 mg; Tablet 5 mg; Tablet 7.5 mg; and Tablet 10 mg

omit from the column headed “Responsible Person” for the brand “Olanzapine-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Olanzapine in each of the forms: Tablet 5 mg (orally disintegrating); and Tablet 10 mg (orally disintegrating)

omit from the column headed “Responsible Person” for the brand “Olanzapine-GA ODT”: **GM** substitute: **GN**

1. Schedule 1, entry for Omeprazole in the form Tablet 20 mg

omit from the column headed “Responsible Person” for the brand “Omeprazole-GA” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Omeprazole in the form Capsule 20 mg

omit from the column headed “Responsible Person” for the brand “Omepro-GA” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Ondansetron in the form Tablet (orally disintegrating) 4 mg

omit from the column headed “Responsible Person” for the brand “Onsetron ODT 4” (twice occurring): **WQ** substitute: **GN**

1. Schedule 1, entry for Ondansetron in the form Tablet (orally disintegrating) 8 mg

omit from the column headed “Responsible Person” for the brand “Onsetron ODT 8” (twice occurring): **WQ** substitute: **GN**

1. Schedule 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 50 mg in 10 mL
   * 1. omit:

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

* + 1. omit from the column headed “Responsible Person” for the brand “Oxaliccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 50 mg

omit from the column headed “Responsible Person” for the brand “Xalox”: **WQ** substitute: **GN**

1. Schedule 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 100 mg in 20 mL
   * 1. omit:

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

* + 1. omit from the column headed “Responsible Person” for the brand “Oxaliccord”: **WQ** substitute: **GN**

1. Schedule 1, entry for Oxaliplatin in the form Powder for I.V. infusion 100 mg

omit from the column headed “Responsible Person” for the brand “Xalox”: **WQ** substitute: **GN**

1. Schedule 1, entry for Oxaliplatin in the form Solution concentrate for I.V. infusion 200 mg in 40 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | 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” for the brand “Oxytrol”: **GM** substitute: **GN**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 30 mg in 5 mL
   * 1. omit:

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

* + 1. omit from the column headed “Responsible Person” for the brand “Plaxel”: **WQ** substitute: **GN**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 100 mg in 16.7 mL
   * 1. omit:

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

* + 1. omit from the column headed “Responsible Person” for the brand “Plaxel”: **WQ** substitute: **GN**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 150 mg in 25 mL

omit from the column headed “Responsible Person” for the brand “Plaxel”: **WQ** substitute: **GN**

1. Schedule 1, entry for Paclitaxel in the form Solution concentrate for I.V. infusion 300 mg in 50 mL
   * 1. omit:

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

* + 1. omit from the column headed “Responsible Person” for the brand “Plaxel”: **WQ** substitute: **GN**

1. Schedule 1, entry for Pamidronic Acid in the form Concentrated injection containing disodium pamidronate 30 mg in 10 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pamidronate Strides | YA | MP NP | C3256 |  | 2 | 0 | 1 |  |  |
|  |  |  |  |  | MP  See Note 1 | C1500 C3341 |  | 2 | 2 | 1 |  | C(100) |

1. Schedule 1, entry for Pamidronic acid in the form Concentrated injection containing disodium pamidronate 90 mg in 10 mL

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Pamidronate Strides | YA | MP  See Note 1 | C1035 C1233  C1500 C3341  C3342 C3343 |  | 1 | 11 | 1 |  | PB(100) |

1. Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 40 mg (as sodium sesquihydrate)

omit from the column headed “Responsible Person” for the brand “Pantoprazole-GA” (twice occurring): **GM** substitute: **UA**

1. Schedule 1, entry for Pantoprazole in the form Tablet (enteric coated) 20 mg (as sodium sesquihydrate)

omit from the column headed “Responsible Person” for the brand “Pantoprazole-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Paracetamol in the form Tablet 500 mg

omit from the column headed “Responsible Person” for the brand “Febridol” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Paraffin in the form Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g

omit from the column headed “Brand” (twice occurring): **Lacri-Lube** substitute: **Refresh Night Time**

1. Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 2 mg

omit from the column headed “Responsible Person” for the brand “Perindopril-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 4 mg

omit from the column headed “Responsible Person” for the brand “Perindopril-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Perindopril in the form Tablet containing perindopril erbumine 8 mg

omit from the column headed “Responsible Person” for the brand “Perindopril-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Phenoxymethylpenicillin in each of the forms: Capsule 250 mg phenoxymethylpenicillin (as potassium); and Capsule 500 mg phenoxymethylpenicillin (as potassium)

omit from the column headed “Responsible Person” for the brand “Cilopen VK” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Pioglitazone in each of the forms: Tablet 15 mg (as hydrochloride); Tablet 30 mg (as hydrochloride); and   
   Tablet 45 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Pioglitazone-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 10 mg

omit from the column headed “Responsible Person” for the brand “Pravastatin-GA 10” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 20 mg

omit from the column headed “Responsible Person” for the brand “Pravastatin-GA 20” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 40 mg

omit from the column headed “Responsible Person” for the brand “Pravastatin-GA 40” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Pravastatin in the form Tablet containing pravastatin sodium 80 mg

omit from the column headed “Responsible Person” for the brand “Pravastatin-GA 80” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Prochlorperazine in the form Tablet containing prochlorperazine maleate 5 mg

omit from the column headed “Responsible Person” for the brand “Prochlorperazine-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Quetiapine in the form Tablet 25 mg (as fumarate)
   * 1. omit from the column headed “Responsible Person” for the brand “Quetiaccord”: **WQ** substitute: **UA**
     2. omit from the column headed “Responsible Person” for the brand “Quipine”: **GM** substitute: **VN**
2. Schedule 1, entry for Quetiapine in the form Tablet 100 mg (as fumarate)
   * 1. omit from the column headed “Responsible Person” for the brand “Quetiaccord”: **WQ** substitute: **UA**
     2. omit from the column headed “Responsible Person” for the brand “Quipine”: **GM** substitute: **VN**
3. Schedule 1, entry for Quetiapine in the form Tablet 200 mg (as fumarate)
   * 1. omit from the column headed “Responsible Person” for the brand “Quetiaccord”: **WQ** substitute: **UA**
     2. omit from the column headed “Responsible Person” for the brand “Quipine”: **GM** substitute: **VN**
4. Schedule 1, entry for Quetiapine in the form Tablet 300 mg (as fumarate)
   * 1. omit from the column headed “Responsible Person” for the brand “Quetiaccord”: **WQ** substitute: **UA**
     2. omit from the column headed “Responsible Person” for the brand “Quipine”: **GM** substitute: **VN**
5. Schedule 1, entry for Quinapril in the form Tablet 5 mg (as hydrochloride)

omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Quinapril Sandoz | SZ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Quinapril in the form Tablet 20 mg (as hydrochloride)
   * 1. omit from the column headed “Responsible Person” for the brand “Quinapril-GA”: **GM** substitute: **UA**
     2. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Quinapril Sandoz | SZ | MP NP |  |  | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 10 mg (enteric coated)
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabeprazole-DRLA | RZ | MP NP | C1337 C1533 |  | 28 | 5 | 28 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Rabeprazole-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Maximum Quantity 30; Number of Repeats 2]*
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabeprazole-DRLA | RZ | MP NP | C1177 C1337 C1533 | P1177 | 30 | 2 | 30 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabeprazole-GA | GM | MP NP | C1177 C1337 C1533 | P1177 | 30 | 2 | 30 |  |  |

1. Schedule 1, entry for Rabeprazole in the form Tablet containing rabeprazole sodium 20 mg (enteric coated) *[Maximum Quantity 30; Number of Repeats 5]*
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabeprazole-DRLA | RZ | MP NP | C1177 C1337 C1533 | P1337 P1533 | 30 | 5 | 30 |  |  |

* + 1. omit:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Rabeprazole-GA | GM | MP NP | C1177 C1337 C1533 | P1337 P1533 | 30 | 5 | 30 |  |  |

1. Schedule 1, entry for Ramipril in the form Capsule 1.25 mg

omit from the column headed “Responsible Person” for the brand “Ramipril-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Ramipril in the form Capsule 2.5 mg

omit from the column headed “Responsible Person” for the brand “Ramipril-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Ramipril in the form Capsule 5 mg

omit from the column headed “Responsible Person” for the brand “Ramipril-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Ramipril in the form Capsule 10 mg

omit from the column headed “Responsible Person” for the brand “Ramipril-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Ranitidine in the form Tablet 150 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Ranoxyl”: **GM** substitute: **GN**

1. Schedule 1, entry for Ranitidine in the form Tablet 300 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Ranoxyl”: **GM** substitute: **GN**

1. Schedule 1, entry for Risedronic Acid in the form Tablet containing risedronate sodium 35 mg

omit from the column headed “Responsible Person” for the brand “Risedronate-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Risperidone in the form Tablet 0.5 mg

omit from the column headed “Responsible Person” for the brand “Risperidone-GA” (twice occurring): **GM** substitute: **GN**

1. Schedule 1, entry for Risperidone in each of the forms: Tablet 1 mg; and Tablet 2 mg

omit from the column headed “Responsible Person” for the brand “Risperidone-GA” (all instances): **GM** substitute: **GN**

1. Schedule 1, entry for Risperidone in the form Tablet 3 mg

omit from the column headed “Responsible Person” for the brand “Risperidone-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Risperidone in the form Tablet 4 mg

omit from the column headed “Responsible Person” for the brand “Risperidone-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Rosuvastatin in the form Tablet 5 mg (as calcium)

omit from the column headed “Responsible Person” for the brand “Rosuvastatin Actavis 5” (twice occurring): **WQ** substitute: **GN**

1. Schedule 1, entry for Rosuvastatin in the form Tablet 10 mg (as calcium)

omit from the column headed “Responsible Person” for the brand “Rosuvastatin Actavis 10” (twice occurring): **WQ** substitute: **GN**

1. Schedule 1, entry for Rosuvastatin in the form Tablet 20 mg (as calcium)

omit from the column headed “Responsible Person” for the brand “Rosuvastatin Actavis 20” (twice occurring): **WQ** substitute: **GN**

1. Schedule 1, entry for Rosuvastatin in the form Tablet 40 mg (as calcium)

omit from the column headed “Responsible Person” for the brand “Rosuvastatin Actavis 40” (twice occurring): **WQ** substitute: **GN**

1. Schedule 1, entry for Roxithromycin in the form Tablet 150 mg *[Maximum Quantity 10; Number of Repeats 0]*
   * 1. omit from the column headed “Responsible Person” for the brand “Roxythromycin-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Roxithromycin SCP 150 | CR | PDP |  |  | 10 | 0 | 10 |  |  |

1. Schedule 1, entry for Roxithromycin in the form Tablet 150 mg *[Maximum Quantity 10; Number of Repeats 1]*
   * 1. omit from the column headed “Responsible Person” for the brand “Roxythromycin-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Roxithromycin SCP 150 | CR | MP NP |  |  | 10 | 1 | 10 |  |  |

1. Schedule 1, entry for Roxithromycin in the form Tablet 300 mg *[Maximum Quantity 5; Number of Repeats 0]*
   * 1. omit from the column headed “Responsible Person” for the brand “Roxythromycin-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Roxithromycin SCP 300 | CR | PDP |  |  | 5 | 0 | 5 |  |  |

1. Schedule 1, entry for Roxithromycin in the form Tablet 300 mg *[Maximum Quantity 5; Number of Repeats 1]*
   * 1. omit from the column headed “Responsible Person” for the brand “Roxythromycin-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Roxithromycin SCP 300 | CR | MP NP |  |  | 5 | 1 | 5 |  |  |

1. Schedule 1, entry for Salbutamol in each of the forms: Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30; and Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30

omit from the column headed “Responsible Person” for the brand “Salbutamol-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Sertraline in each of the forms: Tablet 50 mg (as hydrochloride); and Tablet 100 mg (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Sertraline-GA”: **GM** substitute: **UA**

1. Schedule 1, entry for Simvastatin in each of the forms: Tablet 10 mg; Tablet 20 mg; Tablet 40 mg; and Tablet 80 mg

omit from the column headed “Responsible Person” for the brand “Simvastatin-DP” (all instances): **GM** substitute: **UA**

1. Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) *[Maximum Quantity 4; Number of Repeats 5; Pack Size 2]*

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

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sumatriptan Sandoz | SZ | MP NP | C3233 |  | 4 | 5 | 2 |  |  |

1. Schedule 1, entry for Sumatriptan in the form Tablet 50 mg (as succinate) *[Maximum Quantity 4; Number of Repeats 5; Pack Size 4]*
   * 1. omit from the column headed “Responsible Person” for the brand “Sumatriptan-GA”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Sumatriptan Sandoz | SZ | MP NP | C3233 |  | 4 | 5 | 4 |  |  |

1. Schedule 1, entry for Tamoxifen in the form Tablet 20 mg (as citrate)

omit from the column headed “Responsible Person” for the brand “Tamoxen 20 mg”: **GM** substitute: **GN**

1. Schedule 1, entry for Telapravir in the form Tablet 375 mg
   * 1. omit from the column headed “Maximum Quantity”: **See Note 3** substitute: **252**
     2. omit from the column headed “Number of Repeats”:  **See Note 3** substitute: **0**
2. Schedule 1, entry for Temozolomide in each of the forms: Capsule 5 mg; Capsule 20 mg; Capsule 100 mg; Capsule 140 mg;   
   Capsule 180 mg and Capsule 250 mg

omit from the column headed “Responsible Person” for the brand “Astromide” (all instances): **WQ** substitute: **GN**

1. Schedule 1, entry for Terbinafine in the form Tablet 250 mg (as hydrochloride) *[Maximum Quantity 42; Number of Repeats 0]*
   * 1. omit from the column headed “Responsible Person” for the brand “Terbinafine-GA”: **GM** substitute: **UA**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Terbinafine GH | GQ | MP NP | C2191 C2865 C3244 | P2865 P3244 | 42 | 0 | 42 |  |  |

1. Schedule 1, entry for Terbinafine in the form Tablet 250 mg (as hydrochloride) *[Maximum Quantity 42; Number of Repeats 1]*
   * 1. omit from the column headed “Responsible Person” for the brand “Terbinafine-GA”: **GM** substitute: **UA**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Terbinafine GH | GQ | MP NP | C2191 C2865 C3244 | P2191 | 42 | 1 | 42 |  |  |

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” for the brand “Androderm”: **GM** substitute: **GN**

1. Schedule 1, entry for Timolol in the form Eye gel 1 mg (as maleate) per g, 5 g

omit from the column headed “Responsible Person”: **NV** substitute: **AS**

1. Schedule 1, entry for Topiramate in each of the forms: Tablet 25 mg; Tablet 50 mg; Tablet 100 mg and Tablet 200 mg

omit from the column headed “Responsible Person” for the brand “Topiramate-GA”: **GM** substitute: **GN**

1. Schedule 1, entry for Tramadol in the form Capsule containing tramadol hydrochloride 50 mg *[Maximum Quantity 20;   
   Number of Repeats 0]*
   * 1. omit from the column headed “Responsible Person” for the brand “GA Tramadol 50mg”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Tramadol SCP | CR | MP NP | C1497 C1615 | P1497 | 20 | 0 | 20 |  |  |
|  |  |  |  |  | PDP | C1497 C1615 |  | 20 | 0 | 20 |  |  |

1. Schedule 1, entry for Tramadol in the form Capsule containing tramadol hydrochloride 50 mg *[Maximum Quantity 20;   
   Number of Repeats 2]*
   * 1. omit from the column headed “Responsible Person” for the brand “GA Tramadol 50mg”: **GM** substitute: **GN**
     2. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Tramadol SCP | CR | MP NP | C1497 C1615 | P1615 | 20 | 2 | 20 |  |  |

1. Schedule 1, entry for Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 100 mg

omit from the column headed “Responsible Person” for the brand “GA Tramadol SR 100mg”: **GM** substitute: **GN**

1. Schedule 1, entry for Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 150 mg

omit from the column headed “Responsible Person” for the brand “GA Tramadol SR 150mg”: **GM** substitute: **GN**

1. Schedule 1, entry for Tramadol in the form Tablet (sustained release) containing tramadol hydrochloride 200 mg

omit from the column headed “Responsible Person” for the brand “GA Tramadol SR 200mg”: **GM** substitute: **GN**

1. Schedule 1, entry for Valaciclovir

omit from the column headed “Responsible Person” for the brand “Zelitrex” (all instances): **GM** substitute: **UA**

1. Schedule 1, entry for Vancomycin in each of the forms: Powder for injection 500 mg (500,000 I.U.) (as hydrochloride); and Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride)

omit from the column headed “Responsible Person” for the brand “Vycin IV” (all instances): **WQ** substitute: **GN**

1. Schedule 1, entry for Venlafaxine in the form Capsule (modified release) 75 mg (as hydrochloride)
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Venlafaxine SR SCP 75 | CR | MP NP | C1211 |  | 28 | 5 | 28 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Venlexor XR”: **GM** substitute: **GN**

1. Schedule 1, entry for Venlafaxine in the form Capsule (modified release) 150 mg (as hydrochloride)
   * 1. insert in the columns in the order indicated, and in alphabetical order for the column headed “Brand”:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | Venlafaxine SR SCP 150 | CR | MP NP | C1211 |  | 28 | 5 | 28 |  |  |

* + 1. omit from the column headed “Responsible Person” for the brand “Venlexor XR”: **GM** substitute: **GN**

1. Schedule 1, entry for Vinorelbine in the form Solution for I.V. infusion 10 mg (as tartrate) in 1 mL

omit:

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

1. Schedule 1, entry for Vinorelbine in the form Solution for I.V. infusion 50 mg (as tartrate) in 5 mL

omit:

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

1. Schedule 1, entry for Zolmitriptan

substitute:

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Zolmitriptan | Tablet 2.5 mg | Oral | Zoltrip | QA | MP NP | C3280 |  | 4 | 5 | 2 |  |  |
|  |  |  | Zomig | AP | MP NP | C3280 |  | 4 | 5 | 2 |  |  |

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| GM | Ascent Pharma Pty Ltd | 68 118 734 795 |

1. Schedule 3, entry for Responsible Person Code GN

omit from the column headed “Responsible Person”: **Ascent Pharmaceuticals Limited** substitute: **Actavis Pty Ltd**

1. Schedule 3, after details relevant to Responsible Person Code TX

insert:

|  |  |  |
| --- | --- | --- |
| UA | Actavis Pty Ltd | 17 003 854 626 |

1. Schedule 3, after details relevant to Responsible Person Code VI

insert:

|  |  |  |
| --- | --- | --- |
| VN | Actavis Pty Ltd | 17 003 854 626 |

1. Schedule 3

omit:

|  |  |  |
| --- | --- | --- |
| WQ | Willow Pharmaceuticals Pty Ltd | 80 118 534 704 |

1. Schedule 4, Part 1, entry for Zolmitriptan

omit:

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | C3281 |  |  | Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where adverse events have  occurred with other suitable PBS-listed drugs | Compliance with Authority Required procedures |
|  | C3282 |  |  | Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions have  occurred with other suitable PBS-listed drugs | Compliance with Authority Required procedures |
|  | C3283 |  |  | Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where drug interactions are  expected to occur with other suitable PBS-listed drugs | Compliance with Authority Required procedures |
|  | C3284 |  |  | Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another  suitable PBS-listed drug would cause patient confusion resulting in problems with compliance | Compliance with Authority Required procedures |
|  | C3285 |  |  | Migraine attack in a patient where attacks in the past have usually failed to respond to analgesics, and where transfer to another  suitable PBS-listed drug is likely to result in adverse clinical consequences | Compliance with Authority Required procedures |