

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Pharmaceutical benefits - early supply) Instrument 2015

PB 120 of 2015

Authority

Subsection 84AAA(2) of the *National Health Act 1953* (the Act) provides that in relation to early supply of a pharmaceutical benefit the Minister may specify, by legislative instrument, pharmaceutical items for the purposes of paragraph 84AAA(1)(a) and periods following a previous supply for paragraph 84AAA(1)(b) of the Act.

Purpose

The purpose of this legislative instrument is to specify the pharmaceutical items that are in pharmaceutical benefits for which Pharmaceutical Benefits Scheme (PBS) safety net entitlements will not apply for early supplies, and to specify the period following previous supply.

This legislative instrument revokes and replaces the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 – specification under subsection 84AAA(2)* (PB 30 of 2009) to reflect a change to the Act made by the *National Health Amendment (Pharmaceutical Benefits) Act 2015* (the Amending Act), commencing 1 January 2016. The Amending Act is part of the PBS Access and Sustainability Package.

The change to the Act requires the Minister to specify the early supply period. In this instrument, the period specified is 20 days in all cases, which aligns with the 20 day period previously required by the Act. The instrument also adds pharmaceutical items containing 141 drugs to early supply, as well as making a number of alterations and deletions.

Subsection 84AAA(1) of the Act provides that a supply of a pharmaceutical benefit to a person is an early supply if the pharmaceutical item in the pharmaceutical benefit is specified in an instrument under subsection 84AAA(2) and the supply is made within the period specified (currently 20 days) following a previous supply to the person of the same pharmaceutical benefit, or another pharmaceutical benefit that has the same pharmaceutical item, or another pharmaceutical benefit that is Schedule equivalent.

If an ‘early supply’ of a pharmaceutical benefit occurs, the patient contribution for the early supply does not count towards the PBS safety net threshold, and, if the PBS safety net threshold is passed and PBS safety net would normally allow a concessional or nil contribution, the patient contribution and payments to approved suppliers revert, for that early supply, to pre-PBS safety net amounts.

Early supply does not apply to supplies on prescriptions originating in a hospital, or, supplies of out-patient medication by public hospitals. PBS safety net, including early supply, applies to the Repatriation Pharmaceutical Benefits Scheme (RPBS).

The Pharmaceutical Benefits Advisory Committee (PBAC) has made recommendations to the Minister about what should be specified in this early supply instrument.

Attachment 2 summarises in Tables 1, 2, 3, 4 and 5 additions and changes to listed drugs, forms and circumstances effective from 1 January 2016. Items and circumstances in the revoked instrument but not in this Instrument (deletions) are in Table 6.

Consultation

The PBS Access and Sustainability Package includes measures relating to the Sixth Community Pharmacy Agreement between the Commonwealth of Australia and the Pharmacy Guild of Australia and the Strategic Agreement with the Generic Medicines Industry Association (now known as the Generic and Biosimilar Medicines Association). The measures were negotiated following consultations during the first half of 2015 by the Minister for Health and the Department of Health with stakeholders from the pharmaceutical sector including industry, consumer, medical, pharmacist and wholesaler groups. Organisations represented included Medicines Australia, the Generic Medicines Industry Association, the Consumers Health Forum, NPS MedicineWise, the Australian Medical Association, the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Society of Hospital Pharmacists of Australia, and the National Pharmaceutical Services Association.

The involvement of PBAC constitutes a formal and ongoing process of consultation. The PBAC is the independent expert body, established by section 100A of the Act, which makes recommendations to the Minister about which drugs and medicinal preparations should be available as pharmaceutical benefits. PBAC members are selected from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the Committee, including the option of appointing an industry member. The PBAC has provided advice regarding what should be specified in this Instrument.

This Instrument commences on 1 January 2016.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

ATTACHMENT 1

Section 1

This section provides that the name of the Instrument is the *National Health (Pharmaceutical benefits - early supply) Instrument 2015* and that the Instrument may also be cited as No. PB 120 of 2015.

Section 2

This section provides that the Instrument commences on 1 January 2016.

Section 3

This section provides that the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 - specification under subsection 84AAA(2)*, also referred to as No. PB 30 of 2009, is revoked.

Section 4

This section defines certain terms for the purposes of this determination.

Section 5

This section provides that a pharmaceutical item in a pharmaceutical benefit is specified for paragraph 84AAA(1)(a) of the Act if the name of the listed drug and the form of the listed drug are mentioned in Schedule 1 and all the circumstances identified in section 6 (for subsection 84AAA(3) of the Act) as applying to the benefit are satisfied by virtue that they exist in relation to a benefit that has the item.

Section 6

This section provides that the circumstances which apply to a pharmaceutical benefit that has a pharmaceutical item are that the form (strength, type, size, etc.) is the same as that determined under subsection 85(3) of the Act, the maximum quantity or number of units is that same as determined under paragraph 85A(2)(a), the maximum number of repeats is that same as determined under paragraph 85A(2)(b), and any other circumstance for paragraph 84AAA(3)(b), all as mentioned in the table in Schedule 1. There are no other circumstances currently specified.

Section 7

This section provides that for a pharmaceutical benefit that has the listed drug and form, and the circumstances identified for section 6 in the table in Schedule 1, the number mentioned under the heading ‘Period (days)’ is the period in days for paragraph 84AAA(1)(b) of the Act.

Schedule 1

The schedule contains the specified pharmaceutical items, circumstances and periods.

ATTACHMENT 2

Summary of changes from Schedule 1 of PB 30 of 2009

The changes to Schedule 1 involve additions and deletions to listed drugs and forms, and changes to circumstances, including the maximum quantity or number of units and the maximum number of repeats. The number ‘20’ is included in the column headed ‘Period (days)’ as the period in days for each item.

The listed drug, form, maximum quantity or number of units and maximum number of repeats for a pharmaceutical item are the same as declared and determined under the Act in the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), current as at 1 January 2016.

The changes made by this Instrument are summarised below.

Table 1. Listed drugs added

Listed drug
Abiraterone
Allopurinol
Alogliptin
Alogliptin with metformin
Aspirin
Aurothiomalate
Azathioprine
Benzhexol
Betamethasone
Biperiden
Bupropion
Calcitriol
Calcium
Carbamazepine
Citalopram
Clonazepam
Colestipol
Cyproheptadine
Dabrafenib
Dapagliflozin
Dapagliflozin with metformin
Dapsone
Dasatinib
Denosumab
Desmopressin
Desvenlafaxine
Digoxin
Dimethyl fumarate
Donepezil
Duloxetine
Entacapone
Erlotinib
Escitalopram
Esomeprazole and clarithromycin and amoxicillin
Ethosuximide
Etonogestrel
Exenatide
Fingolimod
Fludrocortisone
Fluvoxamine
Folic acid
Frusemide
Gabapentin
Galantamine

Listed drug
Gestrinone
Glatiramer
Gliclazide
Glimepiride
Goserelin
Griseofulvin
Hydrochlorothiazide
Hydrochlorothiazide with amiloride
Hydrochlorothiazide with triamterene
Hydroxocobalamin
Hydroxychloroquine
Ibandronic acid
Indapamide
Insulin aspart
Insulin aspart with insulin aspart protamine suspension
Insulin detemir
Insulin glargine
Insulin glulisine
Insulin isophane
Insulin lispro
Insulin lispro with insulin lispro protamine suspension
Insulin neutral
Insulin neutral with insulin isophane
Isotretinoin
Ketoprofen
Lacosamide
Lamotrigine
Levetiracetam
Levodopa with carbidopa and entacapone
Levonorgestrel
Levonorgestrel with ethinylestradiol
Linagliptin
Linagliptin with metformin
Liothyronine
Lisdexamfetamine
Medroxyprogesterone
Megestrol
Meloxicam
Memantine
Metformin
Metformin with glibenclamide
Methylprednisolone
Mirtazapine
Moclobemide
Montelukast
Nafarelin
Naproxen

Listed drug
Norethisterone
Norethisterone with ethinyloestradiol
Norethisterone with mestranol
Oxcarbazepine
Oxybutynin
Paracetamol
Paroxetine
Perampanel
Phenobarbitone
Phenytoin
Pioglitazone
Pizotifen
Potassium chloride
Potassium chloride with potassium bicarbonate
Pregabalin
Primidone
Propantheline
Quinagolide
Reboxetine
Rifaximin
Rivastigmine
Rosiglitazone
Rosiglitazone with metformin
Rotigotine
Saxagliptin
Saxagliptin with metformin
Sertraline
Sitagliptin
Sitagliptin with metformin
Sorafenib
Sucralfate
Sulthiame
Sunitinib
Tacrolimus
Terbinafine
Teriflunomide
Tetrabenazine
Thyroxine
Tiagabine
Tiludronic acid
Topiramate
Triamcinolone
Ustekinumab
Valproic acid
Varenicline
Venlafaxine
Vigabatrin

Listed drug
Vildagliptin
Vildagliptin with metformin
Zonisamide

Table 2. Forms for added listed drugs

Listed drug	Form
Abiraterone	Tablet containing abiraterone acetate 250 mg
Allopurinol	Tablet 100 mg
Allopurinol	Tablet 300 mg
Alogliptin	Tablet 12.5 mg (as benzoate)
Alogliptin	Tablet 25 mg (as benzoate)
Alogliptin	Tablet 6.25 mg (as benzoate)
Alogliptin with metformin	Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride
Alogliptin with metformin	Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride
Alogliptin with metformin	Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride
Aspirin	Tablet 100 mg
Aspirin	Tablet, dispersible, 300 mg
Aurothiomalate	Injection containing sodium aurothiomalate 20 mg
Aurothiomalate	Injection containing sodium aurothiomalate 50 mg
Azathioprine	Tablet 25 mg
Azathioprine	Tablet 50 mg
Benzhexol	Tablet containing benzhexol hydrochloride 2 mg
Benzhexol	Tablet containing benzhexol hydrochloride 5 mg
Betamethasone	Injection containing betamethasone acetate 3 mg with betamethasone sodium phosphate 3.9 mg in 1 mL
Biperiden	Tablet containing biperiden hydrochloride 2 mg
Bupropion	Tablet containing bupropion hydrochloride 150 mg (sustained release)
Calcitriol	Capsule 0.25 microgram
Calcium	Tablet 600 mg (as carbonate)
Calcium	Tablet, chewable, 500 mg (as carbonate)
Carbamazepine	Tablet 100 mg
Carbamazepine	Tablet 200 mg
Carbamazepine	Tablet 200 mg (controlled release)
Carbamazepine	Tablet 400 mg (controlled release)
Citalopram	Tablet 20 mg (as hydrobromide)
Citalopram	Tablet 40 mg (as hydrobromide)
Clonazepam	Tablet 2 mg
Clonazepam	Tablet 500 micrograms
Colestipol	Oral powder, sachets containing colestipol hydrochloride 5 g, 120
Cyproheptadine	Tablet containing cyproheptadine hydrochloride 4 mg (anhydrous)
Dabrafenib	Capsule 50 mg (as mesilate)
Dabrafenib	Capsule 75 mg (as mesilate)
Dapagliflozin	Tablet 10 mg (as propanediol monohydrate)
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride

Listed drug	Form
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride
Dapagliflozin with metformin	Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride
Dapsone	Tablet 100 mg
Dapsone	Tablet 25 mg
Dasatinib	Tablet 100 mg
Dasatinib	Tablet 20 mg
Dasatinib	Tablet 50 mg
Dasatinib	Tablet 70 mg
Denosumab	Injection 60 mg in 1 mL pre-filled syringe
Desmopressin	Tablet containing desmopressin acetate 200 micrograms
Desmopressin	Wafer 120 micrograms (as acetate)
Desmopressin	Wafer 240 micrograms (as acetate)
Desvenlafaxine	Tablet (extended release) 100 mg (as succinate)
Desvenlafaxine	Tablet (extended release) 50 mg (as succinate)
Desvenlafaxine	Tablet (modified release) 100 mg
Desvenlafaxine	Tablet (modified release) 100 mg (as benzoate)
Desvenlafaxine	Tablet (modified release) 50 mg
Desvenlafaxine	Tablet (modified release) 50 mg (as benzoate)
Digoxin	Tablet 250 micrograms
Digoxin	Tablet 62.5 micrograms
Dimethyl fumarate	Capsule (modified release) 240 mg
Donepezil	Tablet containing donepezil hydrochloride 10 mg
Donepezil	Tablet containing donepezil hydrochloride 5 mg
Duloxetine	Capsule 60 mg (as hydrochloride)
Entacapone	Tablet 200 mg
Erlotinib	Tablet 100 mg (as hydrochloride)
Erlotinib	Tablet 150 mg (as hydrochloride)
Erlotinib	Tablet 25 mg (as hydrochloride)
Escitalopram	Tablet 10 mg (as oxalate)
Escitalopram	Tablet 20 mg (as oxalate)
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)
Ethosuximide	Capsule 250 mg
Etonogestrel	Subcutaneous implant 68 mg
Exenatide	Injection solution 10 micrograms per dose in pre-filled pen, 60 doses
Exenatide	Injection solution 5 micrograms per dose in pre-filled pen, 60 doses
Fingolimod	Capsule 500 micrograms (as hydrochloride)
Fludrocortisone	Tablet containing fludrocortisone acetate 100 micrograms
Fluvoxamine	Tablet containing fluvoxamine maleate 100 mg
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg
Folic acid	Tablet 5 mg
Folic acid	Tablet 500 micrograms
Frusemide	Tablet 20 mg
Frusemide	Tablet 40 mg
Gabapentin	Capsule 100 mg
Gabapentin	Capsule 300 mg

Listed drug	Form
Gabapentin	Capsule 400 mg
Gabapentin	Tablet 600 mg
Gabapentin	Tablet 800 mg
Galantamine	Capsule (prolonged release) 16 mg (as hydrobromide)
Galantamine	Capsule (prolonged release) 24 mg (as hydrobromide)
Galantamine	Capsule (prolonged release) 8 mg (as hydrobromide)
Gestrinone	Capsule 2.5 mg
Glatiramer	Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe
Gliclazide	Tablet 60 mg (modified release)
Gliclazide	Tablet 80 mg
Glimepiride	Tablet 3 mg
Glimepiride	Tablet 4 mg
Goserelin	Subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe
Goserelin	Subcutaneous implant 3.6 mg (as acetate) in pre-filled injection syringe
Griseofulvin	Tablet 125 mg
Hydrochlorothiazide	Tablet 25 mg
Hydrochlorothiazide with amiloride	Tablet containing hydrochlorothiazide 50 mg with amiloride hydrochloride 5 mg
Hydrochlorothiazide with triamterene	Tablet 25 mg-50 mg
Hydroxocobalamin	Injection 1 mg (as acetate) in 1 mL
Hydroxocobalamin	Injection 1 mg (as chloride) in 1 mL
Hydroxychloroquine	Tablet containing hydroxychloroquine sulfate 200 mg
Ibandronic acid	Tablet 50 mg (as ibandronate sodium monohydrate)
Indapamide	Tablet containing indapamide hemihydrate 1.5 mg (sustained release)
Indapamide	Tablet containing indapamide hemihydrate 2.5 mg
Insulin aspart	Injection (human analogue) 100 units per mL, 10 mL vial
Insulin aspart	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5
Insulin aspart with insulin aspart protamine suspension	Injections (human analogue), cartridges, 30 units-70 units per mL, 3 mL, 5
Insulin detemir	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5
Insulin glargine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5
Insulin glulisine	Injection (human analogue) 100 units per mL, 10 mL
Insulin glulisine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5
Insulin isophane	Injection (bovine) 100 units per mL, 10 mL
Insulin isophane	Injection (human) 100 units per mL, 10 mL
Insulin isophane	Injections (human), cartridges, 100 units per mL, 3 mL, 5
Insulin lispro	Injection (human analogue) 100 units per mL, 10 mL vial
Insulin lispro	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5
Insulin lispro with insulin lispro protamine suspension	Injections (human analogue), cartridges, 25 units-75 units per mL, 3 mL, 5
Insulin lispro with insulin lispro protamine suspension	Injections (human analogue), cartridges, 50 units-50 units per mL, 3 mL, 5
Insulin neutral	Injection (bovine) 100 units per mL, 10 mL
Insulin neutral	Injection (human) 100 units per mL, 10 mL
Insulin neutral	Injections (human), cartridges, 100 units per mL, 3 mL, 5
Insulin neutral with insulin isophane	Injection (human) 30 units-70 units per mL, 10 mL

Listed drug	Form
Insulin neutral with insulin isophane	Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5
Insulin neutral with insulin isophane	Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5
Isotretinoin	Capsule 10 mg
Isotretinoin	Capsule 20 mg
Isotretinoin	Capsule 40 mg
Ketoprofen	Capsule 200 mg (sustained release)
Lacosamide	Tablet 100 mg
Lacosamide	Tablet 150 mg
Lacosamide	Tablet 200 mg
Lamotrigine	Tablet 100 mg
Lamotrigine	Tablet 200 mg
Lamotrigine	Tablet 25 mg
Lamotrigine	Tablet 5 mg
Lamotrigine	Tablet 50 mg
Levetiracetam	Oral solution 100 mg per mL, 300 mL
Levetiracetam	Tablet 1 g
Levetiracetam	Tablet 250 mg
Levetiracetam	Tablet 500 mg
Levodopa with carbidopa and entacapone	Tablet 100 mg-25 mg-200 mg
Levodopa with carbidopa and entacapone	Tablet 125 mg-31.25 mg-200 mg
Levodopa with carbidopa and entacapone	Tablet 150 mg-37.5 mg-200 mg
Levodopa with carbidopa and entacapone	Tablet 200 mg-50 mg-200 mg
Levodopa with carbidopa and entacapone	Tablet 50 mg-12.5 mg-200 mg
Levodopa with carbidopa and entacapone	Tablet 75 mg-18.75 mg-200 mg
Levonorgestrel	Intrauterine drug delivery system 52 mg
Levonorgestrel	Tablets 30 micrograms, 28
Levonorgestrel with ethinyloestradiol	Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets
Levonorgestrel with ethinyloestradiol	Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets
Levonorgestrel with ethinyloestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets
Levonorgestrel with ethinyloestradiol	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets
Linagliptin	Tablet 5 mg
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride
Liothyronine	Tablet containing liothyronine sodium 20 micrograms
Lisdexamfetamine	Capsule containing lisdexamfetamine dimesilate 50 mg
Medroxyprogesterone	Injection containing medroxyprogesterone acetate 150 mg in 1 mL
Medroxyprogesterone	Tablet containing medroxyprogesterone acetate 10 mg
Medroxyprogesterone	Tablet containing medroxyprogesterone acetate 5 mg

Listed drug	Form
Megestrol	Tablet containing megestrol acetate 160 mg
Meloxicam	Capsule 15 mg
Meloxicam	Tablet 15 mg
Memantine	Tablet containing memantine hydrochloride 10 mg
Memantine	Tablet containing memantine hydrochloride 20 mg
Metformin	Tablet (extended release) containing metformin hydrochloride 1 g
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg
Metformin	Tablet containing metformin hydrochloride 1 g
Metformin	Tablet containing metformin hydrochloride 500 mg
Metformin	Tablet containing metformin hydrochloride 850 mg
Metformin with glibenclamide	Tablet containing metformin hydrochloride 250 mg with glibenclamide 1.25 mg
Metformin with glibenclamide	Tablet containing metformin hydrochloride 500 mg with glibenclamide 2.5 mg
Metformin with glibenclamide	Tablet containing metformin hydrochloride 500 mg with glibenclamide 5 mg
Methylprednisolone	Injection containing methylprednisolone acetate 40 mg in 1 mL
Mirtazapine	Tablet 45 mg
Mirtazapine	Tablet 45 mg (orally disintegrating)
Moclobemide	Tablet 150 mg
Moclobemide	Tablet 300 mg
Montelukast	Tablet, chewable, 4 mg (as sodium)
Montelukast	Tablet, chewable, 5 mg (as sodium)
Nafarelin	Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses
Naproxen	Tablet 1 g (sustained release)
Naproxen	Tablet 750 mg (sustained release)
Norethisterone	Tablets 350 micrograms, 28
Norethisterone with ethinyloestradiol	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets
Norethisterone with ethinyloestradiol	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets
Norethisterone with mestranol	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets
Oxcarbazepine	Tablet 600 mg
Oxybutynin	Tablet containing oxybutynin hydrochloride 5 mg
Oxybutynin	Transdermal patches 36 mg, 8
Paracetamol	Tablet 500 mg
Paracetamol	Tablet 665 mg (modified release)
Paroxetine	Tablet 20 mg (as hydrochloride)
Paroxetine	Tablet 20 mg (as mesilate)
Perampanel	Tablet 10 mg (as hemisesquihydrate)
Perampanel	Tablet 12 mg (as hemisesquihydrate)
Perampanel	Tablet 4 mg (as hemisesquihydrate)
Perampanel	Tablet 6 mg (as hemisesquihydrate)
Perampanel	Tablet 8 mg (as hemisesquihydrate)
Phenobarbitone	Tablet 30 mg
Phenytoin	Capsule containing phenytoin sodium 100 mg
Phenytoin	Capsule containing phenytoin sodium 30 mg
Phenytoin	Tablet 50 mg
Pioglitazone	Tablet 45 mg (as hydrochloride)

Listed drug	Form
Pizotifen	Tablet 500 micrograms (as malate)
Potassium chloride	Tablet 600 mg (sustained release)
Potassium chloride with potassium bicarbonate	Tablet, effervescent, 14 mmol potassium and 8 mmol chloride
Pregabalin	Capsule 300 mg
Primidone	Tablet 250 mg
Proprantheline	Tablet containing proprantheline bromide 15 mg
Quinagolide	Tablet 75 micrograms (as hydrochloride)
Reboxetine	Tablet 4 mg (as mesilate)
Rifaximin	Tablet 550 mg
Rivastigmine	Capsule 1.5 mg (as hydrogen tartrate)
Rivastigmine	Capsule 3 mg (as hydrogen tartrate)
Rivastigmine	Capsule 4.5 mg (as hydrogen tartrate)
Rivastigmine	Capsule 6 mg (as hydrogen tartrate)
Rivastigmine	Transdermal patch 18 mg
Rivastigmine	Transdermal patch 27 mg
Rivastigmine	Transdermal patch 9 mg
Rosiglitazone	Tablet 8 mg (as maleate)
Rosiglitazone with metformin	Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride
Rosiglitazone with metformin	Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride
Rosiglitazone with metformin	Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride
Rosiglitazone with metformin	Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride
Rotigotine	Transdermal patch 13.5 mg
Rotigotine	Transdermal patch 4.5 mg
Rotigotine	Transdermal patch 9 mg
Saxagliptin	Tablet 2.5 mg (as hydrochloride)
Saxagliptin	Tablet 5 mg (as hydrochloride)
Saxagliptin with metformin	Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride
Sertraline	Tablet 100 mg (as hydrochloride)
Sertraline	Tablet 50 mg (as hydrochloride)
Sitagliptin	Tablet 100 mg (as phosphate monohydrate)
Sitagliptin	Tablet 25 mg (as phosphate monohydrate)
Sitagliptin	Tablet 50 mg (as phosphate monohydrate)
Sitagliptin with metformin	Tablet (modified release) containing 100 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride
Sitagliptin with metformin	Tablet (modified release) containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride

Listed drug	Form
Sorafenib	Tablet 200 mg (as tosylate)
Sucralfate	Tablet equivalent to 1 g anhydrous sucralfate
Sulthiame	Tablet 200 mg
Sulthiame	Tablet 50 mg
Sunitinib	Capsule 12.5 mg (as malate)
Sunitinib	Capsule 25 mg (as malate)
Sunitinib	Capsule 37.5 mg (as malate)
Sunitinib	Capsule 50 mg (as malate)
Tacrolimus	Capsule 0.5 mg (once daily prolonged release)
Tacrolimus	Capsule 1 mg (once daily prolonged release)
Tacrolimus	Capsule 5 mg (once daily prolonged release)
Terbinafine	Tablet 250 mg (as hydrochloride)
Teriflunomide	Tablet 14 mg
Tetrabenazine	Tablet 25 mg
Thyroxine	Tablet containing 100 micrograms anhydrous thyroxine sodium
Thyroxine	Tablet containing 200 micrograms anhydrous thyroxine sodium
Thyroxine	Tablet containing 50 micrograms anhydrous thyroxine sodium
Thyroxine	Tablet containing 75 micrograms anhydrous thyroxine sodium
Tiagabine	Tablet 10 mg (as hydrochloride)
Tiagabine	Tablet 15 mg (as hydrochloride)
Tiagabine	Tablet 5 mg (as hydrochloride)
Tiludronic acid	Tablet 200 mg (as tiludronate disodium)
Topiramate	Capsule 15 mg
Topiramate	Capsule 25 mg
Topiramate	Capsule 50 mg
Topiramate	Tablet 100 mg
Topiramate	Tablet 200 mg
Topiramate	Tablet 25 mg
Topiramate	Tablet 50 mg
Triamcinolone	Injection containing triamcinolone acetonide 10 mg in 1 mL
Ustekinumab	Injection 45 mg in 0.5 mL
Valproic acid	Tablet (enteric coated) containing sodium valproate 200 mg
Valproic acid	Tablet (enteric coated) containing sodium valproate 500 mg
Varenicline	Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack
Varenicline	Tablet 1 mg (as tartrate)
Venlafaxine	Capsule (modified release) 150 mg (as hydrochloride)
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride)
Vigabatrin	Oral powder, sachet 500 mg
Vigabatrin	Tablet 500 mg
Vildagliptin	Tablet 50 mg
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride
Zonisamide	Capsule 100 mg
Zonisamide	Capsule 25 mg
Zonisamide	Capsule 50 mg

Table 3. Forms added for listed drugs already included

Listed drug	Form
Aciclovir	Tablet 800 mg
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen, 6
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe, 6
Dabigatran etexilate	Capsule 75 mg (as mesilate)
Degarelix	Powder for injection 120 mg (as acetate), 2, injection set
Goserelin and bicalutamide	Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg
Goserelin and bicalutamide	Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 84 tablets bicalutamide 50 mg
Leuprorelin	I.M. injection (3 month modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe
Leuprorelin	I.M. injection (modified release), powder for injection containing leuprorelin acetate 22.5 mg with diluent in pre-filled dual-chamber syringe
Leuprorelin	I.M. injection (modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set
Oestradiol	Tablet 2 mg
Oestradiol	Tablet containing oestradiol valerate 1 mg
Oestradiol	Tablet containing oestradiol valerate 2 mg
Risedronic acid	Tablet containing risedronate sodium 30 mg
Testosterone	I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL
Testosterone	Injection containing testosterone enanthate 250 mg in 1 mL
Testosterone	Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2
Tiotropium	Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)
Triptorelin	Powder for I.M. injection (prolonged release) 11.25 mg (as embonate) with solvent, syringe and needles
Triptorelin	Powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles

Table 4. Added or amended maximum quantities or maximum repeats

Listed drug	Form	Maximum quantity	Maximum number of repeats
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	2	0
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	2	3
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	2	0
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	2	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	2	0
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	2	2
Apixaban	Tablet 2.5 mg	60	0
Apixaban	Tablet 5 mg	28	0
Dabigatran etexilate	Capsule 110 mg (as mesilate)	60	0

Esomeprazole	Capsule (enteric) 20 mg (as magnesium)	30	1
Esomeprazole	Capsule (enteric) 40 mg (as magnesium)	30	1
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	30	1
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	30	1
Imatinib	Tablet 100 mg (as mesylate)	60	2
Imatinib	Tablet 400 mg (as mesylate)	30	2
Lansoprazole	Capsule 30 mg	28	1
Lansoprazole	Tablet 30 mg (orally disintegrating)	28	1
Omeprazole	Capsule 20 mg	30	1
Omeprazole	Tablet 20 mg	30	1
Omeprazole	Tablet 20 mg (as magnesium)	30	1
Pantoprazole	Sachet containing granules 40 mg (as sodium sesquihydrate)	30	2
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	30	2
Pazopanib	Tablet 200 mg (as hydrochloride)	90	2
Pazopanib	Tablet 400 mg (as hydrochloride)	60	2
Rabeprazole	Tablet containing rabeprazole sodium 20 mg (enteric coated)	30	2
Sapropterin	Tablet (soluble) containing sapropterin dihydrochloride 100 mg	180	0
Tamoxifen	Tablet 20 mg (as citrate)	60	5
Temozolomide	Capsule 100 mg	15	2
Temozolomide	Capsule 140 mg	15	2
Temozolomide	Capsule 20 mg	15	2
Temozolomide	Capsule 5 mg	15	2

Table 5. Summary of additions and changes

Listed drug	Form	Maximum quantity	Maximum number of repeats
Abiraterone	Tablet containing abiraterone acetate 250 mg	120	2
Aciclovir	Tablet 800 mg	120	5
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	2	0
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	2	3
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	2	0
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen	2	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled pen, 6	1	0
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	2	0
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe	2	2
Adalimumab	Injection 40 mg in 0.8 mL pre-filled syringe, 6	1	0
Allopurinol	Tablet 100 mg	200	2
Allopurinol	Tablet 300 mg	60	2
Alogliptin	Tablet 12.5 mg (as benzoate)	28	5
Alogliptin	Tablet 25 mg (as benzoate)	28	5
Alogliptin	Tablet 6.25 mg (as benzoate)	28	5
Alogliptin with metformin	Tablet containing 12.5 mg alogliptin (as benzoate) with 1 g metformin hydrochloride	56	5
Alogliptin with metformin	Tablet containing 12.5 mg alogliptin (as benzoate) with 500 mg metformin hydrochloride	56	5
Alogliptin with metformin	Tablet containing 12.5 mg alogliptin (as benzoate) with 850 mg metformin hydrochloride	56	5
Apixaban	Tablet 2.5 mg	60	0
Apixaban	Tablet 5 mg	28	0

Listed drug	Form	Maximum quantity	Maximum number of repeats
Aspirin	Tablet 100 mg	112	1
Aspirin	Tablet, dispersible, 300 mg	96	0
Aurothiomalate	Injection containing sodium aurothiomalate 20 mg	10	1
Aurothiomalate	Injection containing sodium aurothiomalate 50 mg	10	1
Azathioprine	Tablet 25 mg	100	5
Azathioprine	Tablet 50 mg	100	5
Benzhexol	Tablet containing benzhexol hydrochloride 2 mg	200	2
Benzhexol	Tablet containing benzhexol hydrochloride 5 mg	200	1
Betamethasone	Injection containing betamethasone acetate 3 mg with betamethasone sodium phosphate 3.9 mg in 1 mL	5	0
Biperiden	Tablet containing biperiden hydrochloride 2 mg	200	2
Bupropion	Tablet containing bupropion hydrochloride 150 mg (sustained release)	30	0
Bupropion	Tablet containing bupropion hydrochloride 150 mg (sustained release)	90	0
Calcitriol	Capsule 0.25 microgram	100	3
Calcium	Tablet 600 mg (as carbonate)	240	1
Calcium	Tablet, chewable, 500 mg (as carbonate)	240	1
Carbamazepine	Tablet 100 mg	200	0
Carbamazepine	Tablet 100 mg	200	2
Carbamazepine	Tablet 200 mg	200	0
Carbamazepine	Tablet 200 mg	200	2
Carbamazepine	Tablet 200 mg (controlled release)	200	0
Carbamazepine	Tablet 200 mg (controlled release)	200	2
Carbamazepine	Tablet 400 mg (controlled release)	200	0
Carbamazepine	Tablet 400 mg (controlled release)	200	2
Citalopram	Tablet 20 mg (as hydrobromide)	28	5
Citalopram	Tablet 40 mg (as hydrobromide)	28	5
Clonazepam	Tablet 2 mg	200	2
Clonazepam	Tablet 500 micrograms	200	2
Colestipol	Oral powder, sachets containing colestipol hydrochloride 5 g, 120	1	5
Colestipol	Oral powder, sachets containing colestipol hydrochloride 5 g, 120	1	11
Cyproheptadine	Tablet containing cyproheptadine hydrochloride 4 mg (anhydrous)	100	2
Dabigatran etexilate	Capsule 110 mg (as mesilate)	60	0
Dabigatran etexilate	Capsule 75 mg (as mesilate)	60	0
Dabrafenib	Capsule 50 mg (as mesilate)	120	3
Dabrafenib	Capsule 50 mg (as mesilate)	120	5
Dabrafenib	Capsule 75 mg (as mesilate)	120	3
Dabrafenib	Capsule 75 mg (as mesilate)	120	5
Dapagliflozin	Tablet 10 mg (as propanediol monohydrate)	28	5
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride	28	5
Dapagliflozin with metformin	Tablet (modified release) containing 10 mg dapagliflozin (as propanediol monohydrate) with 500 mg metformin hydrochloride	28	5

Listed drug	Form	Maximum quantity	Maximum number of repeats
Dapagliflozin with metformin	Tablet (modified release) containing 5 mg dapagliflozin (as propanediol monohydrate) with 1000 mg metformin hydrochloride	56	5
Dapsone	Tablet 100 mg	100	1
Dapsone	Tablet 25 mg	100	1
Dasatinib	Tablet 100 mg	30	2
Dasatinib	Tablet 100 mg	30	5
Dasatinib	Tablet 20 mg	60	2
Dasatinib	Tablet 20 mg	60	5
Dasatinib	Tablet 50 mg	60	2
Dasatinib	Tablet 50 mg	60	5
Dasatinib	Tablet 70 mg	60	2
Dasatinib	Tablet 70 mg	60	5
Degarelix	Powder for injection 120 mg (as acetate), 2, injection set	1	0
Denosumab	Injection 60 mg in 1 mL pre-filled syringe	1	0
Desmopressin	Tablet containing desmopressin acetate 200 micrograms	30	5
Desmopressin	Tablet containing desmopressin acetate 200 micrograms	90	5
Desmopressin	Wafer 120 micrograms (as acetate)	30	5
Desmopressin	Wafer 240 micrograms (as acetate)	30	5
Desvenlafaxine	Tablet (extended release) 100 mg (as succinate)	28	5
Desvenlafaxine	Tablet (extended release) 50 mg (as succinate)	28	5
Desvenlafaxine	Tablet (modified release) 100 mg	28	5
Desvenlafaxine	Tablet (modified release) 100 mg (as benzoate)	28	5
Desvenlafaxine	Tablet (modified release) 50 mg	28	5
Desvenlafaxine	Tablet (modified release) 50 mg (as benzoate)	28	5
Digoxin	Tablet 250 micrograms	100	1
Digoxin	Tablet 62.5 micrograms	200	1
Dimethyl fumarate	Capsule (modified release) 240 mg	56	5
Donepezil	Tablet containing donepezil hydrochloride 10 mg	28	5
Donepezil	Tablet containing donepezil hydrochloride 5 mg	28	5
Duloxetine	Capsule 60 mg (as hydrochloride)	28	5
Entacapone	Tablet 200 mg	200	4
Erlotinib	Tablet 100 mg (as hydrochloride)	30	3
Erlotinib	Tablet 150 mg (as hydrochloride)	30	3
Erlotinib	Tablet 25 mg (as hydrochloride)	30	3
Escitalopram	Tablet 10 mg (as oxalate)	28	5
Escitalopram	Tablet 20 mg (as oxalate)	28	5
Esomeprazole	Capsule (enteric) 20 mg (as magnesium)	30	1
Esomeprazole	Capsule (enteric) 40 mg (as magnesium)	30	1
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate)	30	1
Esomeprazole	Tablet (enteric coated) 40 mg (as magnesium trihydrate)	30	1
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)	1	0
Ethosuximide	Capsule 250 mg	200	2
Etonogestrel	Subcutaneous implant 68 mg	1	0

Listed drug	Form	Maximum quantity	Maximum number of repeats
Exenatide	Injection solution 10 micrograms per dose in pre-filled pen, 60 doses	1	5
Exenatide	Injection solution 5 micrograms per dose in pre-filled pen, 60 doses	1	5
Fingolimod	Capsule 500 micrograms (as hydrochloride)	28	5
Fludrocortisone	Tablet containing fludrocortisone acetate 100 micrograms	200	1
Fluvoxamine	Tablet containing fluvoxamine maleate 100 mg	30	5
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg	30	5
Folic acid	Tablet 5 mg	200	1
Folic acid	Tablet 500 micrograms	200	0
Frusemide	Tablet 20 mg	100	1
Frusemide	Tablet 40 mg	100	1
Gabapentin	Capsule 100 mg	100	5
Gabapentin	Capsule 300 mg	100	5
Gabapentin	Capsule 400 mg	100	5
Gabapentin	Tablet 600 mg	100	5
Gabapentin	Tablet 800 mg	100	5
Galantamine	Capsule (prolonged release) 16 mg (as hydrobromide)	28	5
Galantamine	Capsule (prolonged release) 24 mg (as hydrobromide)	28	5
Galantamine	Capsule (prolonged release) 8 mg (as hydrobromide)	28	5
Gestrinone	Capsule 2.5 mg	8	5
Glatiramer	Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe	28	5
Gliclazide	Tablet 60 mg (modified release)	60	5
Gliclazide	Tablet 80 mg	100	5
Glimepiride	Tablet 3 mg	30	5
Glimepiride	Tablet 4 mg	30	5
Goserelin	Subcutaneous implant (long acting) 10.8 mg (as acetate) in pre-filled injection syringe	1	1
Goserelin	Subcutaneous implant 3.6 mg (as acetate) in pre-filled injection syringe	1	5
Goserelin and bicalutamide	Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 28 tablets bicalutamide 50 mg	1	0
Goserelin and bicalutamide	Pack containing 1 subcutaneous implant containing goserelin 10.8 mg (as acetate) in pre-filled injection syringe and 84 tablets bicalutamide 50 mg	1	1
Griseofulvin	Tablet 125 mg	100	2
Hydrochlorothiazide	Tablet 25 mg	100	1
Hydrochlorothiazide with amiloride	Tablet containing hydrochlorothiazide 50 mg with amiloride hydrochloride 5 mg	100	1
Hydrochlorothiazide with triamterene	Tablet 25 mg-50 mg	100	1
Hydroxocobalamin	Injection 1 mg (as acetate) in 1 mL	3	0
Hydroxocobalamin	Injection 1 mg (as chloride) in 1 mL	3	0
Hydroxychloroquine	Tablet containing hydroxychloroquine sulfate 200 mg	100	1
Ibandronic acid	Tablet 50 mg (as ibandronate sodium monohydrate)	28	2
Imatinib	Tablet 100 mg (as mesylate)	60	2
Imatinib	Tablet 400 mg (as mesylate)	30	2

Listed drug	Form	Maximum quantity	Maximum number of repeats
Indapamide	Tablet containing indapamide hemihydrate 1.5 mg (sustained release)	90	1
Indapamide	Tablet containing indapamide hemihydrate 2.5 mg	90	1
Insulin aspart	Injection (human analogue) 100 units per mL, 10 mL vial	5	2
Insulin aspart	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin aspart with insulin aspart protamine suspension	Injections (human analogue), cartridges, 30 units-70 units per mL, 3 mL, 5	5	1
Insulin detemir	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin glargine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin glulisine	Injection (human analogue) 100 units per mL, 10 mL	5	2
Insulin glulisine	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin isophane	Injection (bovine) 100 units per mL, 10 mL	5	2
Insulin isophane	Injection (human) 100 units per mL, 10 mL	5	2
Insulin isophane	Injections (human), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin lispro	Injection (human analogue) 100 units per mL, 10 mL vial	5	2
Insulin lispro	Injections (human analogue), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin lispro with insulin lispro protamine suspension	Injections (human analogue), cartridges, 25 units-75 units per mL, 3 mL, 5	5	1
Insulin lispro with insulin lispro protamine suspension	Injections (human analogue), cartridges, 50 units-50 units per mL, 3 mL, 5	5	1
Insulin neutral	Injection (bovine) 100 units per mL, 10 mL	5	2
Insulin neutral	Injection (human) 100 units per mL, 10 mL	5	2
Insulin neutral	Injections (human), cartridges, 100 units per mL, 3 mL, 5	5	1
Insulin neutral with insulin isophane	Injection (human) 30 units-70 units per mL, 10 mL	5	2
Insulin neutral with insulin isophane	Injections (human), cartridges, 30 units-70 units per mL, 3 mL, 5	5	1
Insulin neutral with insulin isophane	Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5	5	1
Isotretinoin	Capsule 10 mg	60	3
Isotretinoin	Capsule 20 mg	60	3
Isotretinoin	Capsule 40 mg	30	3
Ketoprofen	Capsule 200 mg (sustained release)	28	0
Ketoprofen	Capsule 200 mg (sustained release)	28	3
Lacosamide	Tablet 100 mg	56	5
Lacosamide	Tablet 150 mg	56	5
Lacosamide	Tablet 200 mg	56	5
Lamotrigine	Tablet 100 mg	56	5
Lamotrigine	Tablet 200 mg	56	5
Lamotrigine	Tablet 25 mg	56	5
Lamotrigine	Tablet 5 mg	56	5
Lamotrigine	Tablet 50 mg	56	5
Lansoprazole	Capsule 30 mg	28	1

Listed drug	Form	Maximum quantity	Maximum number of repeats
Lansoprazole	Tablet 30 mg (orally disintegrating)	28	1
Leuprorelin	I.M. injection (3 month modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe	1	1
Leuprorelin	I.M. injection (modified release), powder for injection containing leuprorelin acetate 22.5 mg with diluent in pre-filled dual-chamber syringe	1	1
Leuprorelin	I.M. injection (modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe	1	1
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 22.5 mg, injection set	1	1
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 30 mg, injection set	1	1
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 45 mg, injection set	1	0
Leuprorelin	Suspension for subcutaneous injection (modified release) containing leuprorelin acetate 7.5 mg, injection set	1	5
Levetiracetam	Oral solution 100 mg per mL, 300 mL	1	5
Levetiracetam	Tablet 1 g	60	5
Levetiracetam	Tablet 250 mg	60	5
Levetiracetam	Tablet 500 mg	60	5
Levodopa with carbidopa and entacapone	Tablet 100 mg-25 mg-200 mg	200	4
Levodopa with carbidopa and entacapone	Tablet 125 mg-31.25 mg-200 mg	200	4
Levodopa with carbidopa and entacapone	Tablet 150 mg-37.5 mg-200 mg	200	4
Levodopa with carbidopa and entacapone	Tablet 200 mg-50 mg-200 mg	200	4
Levodopa with carbidopa and entacapone	Tablet 50 mg-12.5 mg-200 mg	200	4
Levodopa with carbidopa and entacapone	Tablet 75 mg-18.75 mg-200 mg	200	4
Levonorgestrel	Intrauterine drug delivery system 52 mg	1	0
Levonorgestrel	Tablets 30 micrograms, 28	4	2
Levonorgestrel with ethinyloestradiol	Pack containing 21 tablets 100 micrograms-20 micrograms and 7 inert tablets	4	2
Levonorgestrel with ethinyloestradiol	Pack containing 21 tablets 125 micrograms-50 micrograms and 7 inert tablets	4	2
Levonorgestrel with ethinyloestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets	4	2
Levonorgestrel with ethinyloestradiol	Pack containing 6 tablets 50 micrograms-30 micrograms, 5 tablets 75 micrograms-40 micrograms, 10 tablets 125 micrograms-30 micrograms and 7 inert tablets	4	2
Linagliptin	Tablet 5 mg	30	5
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 1000 mg metformin hydrochloride	60	5

Listed drug	Form	Maximum quantity	Maximum number of repeats
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 500 mg metformin hydrochloride	60	5
Linagliptin with metformin	Tablet containing 2.5 mg linagliptin with 850 mg metformin hydrochloride	60	5
Liothyronine	Tablet containing liothyronine sodium 20 micrograms	100	2
Lisdexamfetamine	Capsule containing lisdexamfetamine dimesilate 50 mg	30	5
Medroxyprogesterone	Injection containing medroxyprogesterone acetate 150 mg in 1 mL	1	1
Medroxyprogesterone	Tablet containing medroxyprogesterone acetate 10 mg	30	2
Medroxyprogesterone	Tablet containing medroxyprogesterone acetate 10 mg	100	2
Medroxyprogesterone	Tablet containing medroxyprogesterone acetate 5 mg	56	2
Megestrol	Tablet containing megestrol acetate 160 mg	30	2
Meloxicam	Capsule 15 mg	30	3
Meloxicam	Tablet 15 mg	30	3
Memantine	Tablet containing memantine hydrochloride 10 mg	56	5
Memantine	Tablet containing memantine hydrochloride 20 mg	28	5
Metformin	Tablet (extended release) containing metformin hydrochloride 1 g	60	5
Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg	120	5
Metformin	Tablet containing metformin hydrochloride 1 g	90	5
Metformin	Tablet containing metformin hydrochloride 500 mg	100	5
Metformin	Tablet containing metformin hydrochloride 850 mg	60	5
Metformin with glibenclamide	Tablet containing metformin hydrochloride 250 mg with glibenclamide 1.25 mg	90	5
Metformin with glibenclamide	Tablet containing metformin hydrochloride 500 mg with glibenclamide 2.5 mg	90	5
Metformin with glibenclamide	Tablet containing metformin hydrochloride 500 mg with glibenclamide 5 mg	90	5
Methylprednisolone	Injection containing methylprednisolone acetate 40 mg in 1 mL	5	0
Mirtazapine	Tablet 45 mg	30	5
Mirtazapine	Tablet 45 mg (orally disintegrating)	30	5
Moclobemide	Tablet 150 mg	60	5
Moclobemide	Tablet 300 mg	60	5
Montelukast	Tablet, chewable, 4 mg (as sodium)	28	5
Montelukast	Tablet, chewable, 5 mg (as sodium)	28	5
Nafarelin	Nasal spray (pump pack) 200 micrograms (as acetate) per dose, 60 doses	1	5
Naproxen	Tablet 1 g (sustained release)	28	0
Naproxen	Tablet 1 g (sustained release)	28	3
Naproxen	Tablet 750 mg (sustained release)	28	0
Naproxen	Tablet 750 mg (sustained release)	28	3
Norethisterone	Tablets 350 micrograms, 28	4	2
Norethisterone with ethinyloestradiol	Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets	4	2
Norethisterone with ethinyloestradiol	Pack containing 21 tablets 500 micrograms-35 micrograms and 7 inert tablets	4	2
Norethisterone with mestranol	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets	4	2
Oestradiol	Tablet 2 mg	56	2

Listed drug	Form	Maximum quantity	Maximum number of repeats
Oestradiol	Tablet containing oestradiol valerate 1 mg	56	2
Oestradiol	Tablet containing oestradiol valerate 2 mg	56	2
Omeprazole	Capsule 20 mg	30	1
Omeprazole	Tablet 20 mg	30	1
Omeprazole	Tablet 20 mg (as magnesium)	30	1
Oxcarbazepine	Tablet 600 mg	100	5
Oxybutynin	Tablet containing oxybutynin hydrochloride 5 mg	100	5
Oxybutynin	Transdermal patches 36 mg, 8	1	5
Pantoprazole	Sachet containing granules 40 mg (as sodium sesquihydrate)	30	2
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	30	2
Paracetamol	Tablet 500 mg	300	0
Paracetamol	Tablet 665 mg (modified release)	192	5
Paroxetine	Tablet 20 mg (as hydrochloride)	30	5
Paroxetine	Tablet 20 mg (as mesilate)	30	5
Pazopanib	Tablet 200 mg (as hydrochloride)	90	2
Pazopanib	Tablet 400 mg (as hydrochloride)	60	2
Perampanel	Tablet 10 mg (as hemisesquihydrate)	28	5
Perampanel	Tablet 12 mg (as hemisesquihydrate)	28	5
Perampanel	Tablet 4 mg (as hemisesquihydrate)	28	5
Perampanel	Tablet 6 mg (as hemisesquihydrate)	28	5
Perampanel	Tablet 8 mg (as hemisesquihydrate)	28	5
Phenobarbitone	Tablet 30 mg	200	4
Phenytoin	Capsule containing phenytoin sodium 100 mg	200	2
Phenytoin	Capsule containing phenytoin sodium 30 mg	200	2
Phenytoin	Tablet 50 mg	200	2
Pioglitazone	Tablet 45 mg (as hydrochloride)	28	5
Pizotifen	Tablet 500 micrograms (as malate)	100	2
Potassium chloride	Tablet 600 mg (sustained release)	200	1
Potassium chloride with potassium bicarbonate	Tablet, effervescent, 14 mmol potassium and 8 mmol chloride	60	1
Pregabalin	Capsule 300 mg	56	5
Primidone	Tablet 250 mg	200	2
Propantheline	Tablet containing propantheline bromide 15 mg	200	5
Quinagolide	Tablet 75 micrograms (as hydrochloride)	30	5
Rabeprazole	Tablet containing rabeprazole sodium 20 mg (enteric coated)	30	2
Reboxetine	Tablet 4 mg (as mesilate)	60	5
Rifaximin	Tablet 550 mg	56	5
Risedronic acid	Tablet containing risedronate sodium 30 mg	28	1
Rivastigmine	Capsule 1.5 mg (as hydrogen tartrate)	56	5
Rivastigmine	Capsule 3 mg (as hydrogen tartrate)	56	5
Rivastigmine	Capsule 4.5 mg (as hydrogen tartrate)	56	5
Rivastigmine	Capsule 6 mg (as hydrogen tartrate)	56	5
Rivastigmine	Transdermal patch 18 mg	30	5
Rivastigmine	Transdermal patch 27 mg	30	5
Rivastigmine	Transdermal patch 9 mg	30	5

Listed drug	Form	Maximum quantity	Maximum number of repeats
Rosiglitazone	Tablet 8 mg (as maleate)	28	5
Rosiglitazone with metformin	Tablet containing 2 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride	56	5
Rosiglitazone with metformin	Tablet containing 2 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride	56	5
Rosiglitazone with metformin	Tablet containing 4 mg rosiglitazone (as maleate) with 1 g metformin hydrochloride	56	5
Rosiglitazone with metformin	Tablet containing 4 mg rosiglitazone (as maleate) with 500 mg metformin hydrochloride	56	5
Rotigotine	Transdermal patch 13.5 mg	28	5
Rotigotine	Transdermal patch 4.5 mg	28	5
Rotigotine	Transdermal patch 9 mg	28	5
Sapropterin	Tablet (soluble) containing sapropterin dihydrochloride 100 mg	180	0
Saxagliptin	Tablet 2.5 mg (as hydrochloride)	28	5
Saxagliptin	Tablet 5 mg (as hydrochloride)	28	5
Saxagliptin with metformin	Tablet (modified release) containing 2.5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	56	5
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 1000 mg metformin hydrochloride	28	5
Saxagliptin with metformin	Tablet (modified release) containing 5 mg saxagliptin (as hydrochloride) with 500 mg metformin hydrochloride	28	5
Sertraline	Tablet 100 mg (as hydrochloride)	30	5
Sertraline	Tablet 50 mg (as hydrochloride)	30	5
Sitagliptin	Tablet 100 mg (as phosphate monohydrate)	28	5
Sitagliptin	Tablet 25 mg (as phosphate monohydrate)	28	5
Sitagliptin	Tablet 50 mg (as phosphate monohydrate)	28	5
Sitagliptin with metformin	Tablet (modified release) containing 100 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride	28	5
Sitagliptin with metformin	Tablet (modified release) containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride	56	5
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 1000 mg metformin hydrochloride	56	5
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 500 mg metformin hydrochloride	56	5
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin (as phosphate monohydrate) with 850 mg metformin hydrochloride	56	5
Sorafenib	Tablet 200 mg (as tosylate)	120	2
Sorafenib	Tablet 200 mg (as tosylate)	120	5
Sucralfate	Tablet equivalent to 1 g anhydrous sucralfate	120	2
Sulthiame	Tablet 200 mg	200	2
Sulthiame	Tablet 50 mg	200	2
Sunitinib	Capsule 12.5 mg (as malate)	28	1
Sunitinib	Capsule 12.5 mg (as malate)	28	2
Sunitinib	Capsule 12.5 mg (as malate)	28	3
Sunitinib	Capsule 12.5 mg (as malate)	28	5
Sunitinib	Capsule 25 mg (as malate)	28	1
Sunitinib	Capsule 25 mg (as malate)	28	2
Sunitinib	Capsule 25 mg (as malate)	28	3

Listed drug	Form	Maximum quantity	Maximum number of repeats
Sunitinib	Capsule 25 mg (as malate)	28	5
Sunitinib	Capsule 37.5 mg (as malate)	28	1
Sunitinib	Capsule 37.5 mg (as malate)	28	2
Sunitinib	Capsule 37.5 mg (as malate)	28	3
Sunitinib	Capsule 37.5 mg (as malate)	28	5
Sunitinib	Capsule 50 mg (as malate)	28	1
Sunitinib	Capsule 50 mg (as malate)	28	2
Sunitinib	Capsule 50 mg (as malate)	28	3
Sunitinib	Capsule 50 mg (as malate)	28	5
Tacrolimus	Capsule 0.5 mg (once daily prolonged release)	30	3
Tacrolimus	Capsule 1 mg (once daily prolonged release)	60	3
Tacrolimus	Capsule 5 mg (once daily prolonged release)	30	3
Tamoxifen	Tablet 20 mg (as citrate)	60	5
Temozolomide	Capsule 100 mg	15	2
Temozolomide	Capsule 140 mg	15	2
Temozolomide	Capsule 20 mg	15	2
Temozolomide	Capsule 5 mg	15	2
Terbinafine	Tablet 250 mg (as hydrochloride)	42	0
Terbinafine	Tablet 250 mg (as hydrochloride)	42	1
Teriflunomide	Tablet 14 mg	28	5
Testosterone	I.M. injection containing testosterone undecanoate 1,000 mg in 4 mL	1	1
Testosterone	Injection containing testosterone enanthate 250 mg in 1 mL	3	3
Testosterone	Transdermal gel (pump pack) 12.5 mg per 1.25 g dose, 60 doses, 2	1	4
Tetrabenazine	Tablet 25 mg	112	5
Thyroxine	Tablet containing 100 micrograms anhydrous thyroxine sodium	200	1
Thyroxine	Tablet containing 200 micrograms anhydrous thyroxine sodium	200	1
Thyroxine	Tablet containing 50 micrograms anhydrous thyroxine sodium	200	1
Thyroxine	Tablet containing 75 micrograms anhydrous thyroxine sodium	200	1
Tiagabine	Tablet 10 mg (as hydrochloride)	100	5
Tiagabine	Tablet 15 mg (as hydrochloride)	100	5
Tiagabine	Tablet 5 mg (as hydrochloride)	100	5
Tiludronic acid	Tablet 200 mg (as tiludronate disodium)	56	2
Tiotropium	Solution for oral inhalation 2.5 micrograms (as bromide monohydrate) per actuation (60 actuations)	1	5
Topiramate	Capsule 15 mg	60	5
Topiramate	Capsule 25 mg	60	5
Topiramate	Capsule 50 mg	60	5
Topiramate	Tablet 100 mg	60	5
Topiramate	Tablet 200 mg	60	5
Topiramate	Tablet 25 mg	60	5
Topiramate	Tablet 50 mg	60	5

Listed drug	Form	Maximum quantity	Maximum number of repeats
Triamcinolone	Injection containing triamcinolone acetonide 10 mg in 1 mL	5	0
Triptorelin	Powder for I.M. injection (prolonged release) 11.25 mg (as embonate) with solvent, syringe and needles	1	1
Triptorelin	Powder for I.M. injection (prolonged release) 22.5 mg (as embonate) with solvent, syringe and needles	1	0
Ustekinumab	Injection 45 mg in 0.5 mL	1	1
Valproic acid	Tablet (enteric coated) containing sodium valproate 200 mg	200	2
Valproic acid	Tablet (enteric coated) containing sodium valproate 500 mg	200	2
Varenicline	Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack	1	0
Varenicline	Tablet 1 mg (as tartrate)	56	2
Varenicline	Tablet 1 mg (as tartrate)	112	0
Venlafaxine	Capsule (modified release) 150 mg (as hydrochloride)	28	5
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride)	28	5
Vigabatrin	Oral powder, sachet 500 mg	60	5
Vigabatrin	Tablet 500 mg	100	5
Vildagliptin	Tablet 50 mg	60	5
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 1000 mg metformin hydrochloride	60	5
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 500 mg metformin hydrochloride	60	5
Vildagliptin with metformin	Tablet containing 50 mg vildagliptin with 850 mg metformin hydrochloride	60	5
Zonisamide	Capsule 100 mg	112	5
Zonisamide	Capsule 25 mg	56	5
Zonisamide	Capsule 50 mg	56	5

Table 6. Deletions

Listed drug	Form	Maximum quantity	Maximum number of repeats
Aripiprazole	Powder for injection 300 mg (as monohydrate) with diluent	1	5
Aripiprazole	Powder for injection 400 mg (as monohydrate) with diluent	1	5
Denosumab	Injection 120 mg in 1.7 mL	1	5
Ponatinib	Tablet 15 mg (as hydrochloride)	60	5
Ponatinib	Tablet 45 mg (as hydrochloride)	30	5
Tofacitinib	Tablet 5 mg	56	5

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Pharmaceutical benefits – early supply) Instrument 2015 (PB 120 of 2015)

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

This Instrument specifies the pharmaceutical items that are in pharmaceutical benefits for which Pharmaceutical Benefits Scheme (PBS) safety net entitlements will not apply for early supplies, and to specify the period following a previous supply that constitutes an early supply.

An early supply occurs if a specified pharmaceutical benefit is resupplied within the specified period after a previous supply of the same or an equivalent pharmaceutical benefit.

The effect of being an early supply is that the patient payment for the early supply prescription does not count towards the PBS safety net threshold, and, if the PBS safety net threshold has been reached and PBS safety net would normally allow a concessional or nil contribution, the patient payment and the amount paid by the Commonwealth to the pharmacy or other approved supplier revert to pre-PBS safety net amounts.

The Instrument implements a measure to expand application of PBS safety net early supply rules contained in the PBS Access and Sustainability Package (the Package) announced by the Australian Government in May 2015.

Human rights implications

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS assists with advancement of this human right by providing subsidised access to medicines for Australians. The role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

The extension of safety net early supply rules to apply to a wider range of medicines will mean that safety net benefits will not apply for resupplies of more medicines, if they are obtained as early supplies. However, this is justified as early supply arrangements support the quality use of medicines and responsible use of PBS entitlements as well as discouraging waste and reducing the quantity of unused medicines in the community. The extension of early supply will also result in savings to the PBS. The listing of new and innovative medicines relies on using PBS funding responsibly and keeping the PBS sustainable.

The measures in the Package, including early supply changes, are the result of consultation and negotiation with stakeholders across the PBS supply chain, including the pharmaceutical industry, pharmacy groups and consumers. Together, the measures provide a fair and balanced approach in which benefits and savings are shared across PBS stakeholders to ensure continued and improved access to medicines for consumers.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

The Hon Sussan Ley MP, Minister for Health