EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2013 (No. 11)

PB 61 of 2013

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88, and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to make changes to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, maximum quantities, numbers of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). The Minister may also determine a brand of a pharmaceutical item (subsection 85(6)). The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

Subsection 88(1) provides that a medical practitioner is authorised to prescribe a pharmaceutical benefit. Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

Subsection 85(7) provides that the Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit.

Paragraph 85A(2)(a) allows the Minister to determine the maximum quantity or number of units of the pharmaceutical item in a pharmaceutical benefit (or of the pharmaceutical benefit where there is no pharmaceutical item) that may, in one prescription, be directed to be supplied on one occasion. Paragraph 85A(2)(b) also allows the Minister to determine the maximum number of occasions on which the supply of the pharmaceutical benefit may, in one prescription, be directed to be repeated. The maximum quantities and repeats may be determined for all purposes or for particular purposes.

Supplying pharmaceutical benefits

Subsection 85(2A) provides that the Minister must declare that a particular listed drug can only be provided under a special arrangement under section 100 if the PBAC has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

Paragraph 85(8)(a) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100.

Paragraph 85(8)(b) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under special arrangements under section 100 for one or more of the circumstances determined for that pharmaceutical benefit under subsection 85(7).

Subsection 85(2AA) provides that the Minister must declare that a particular listed drug can only be provided under one or more of the prescriber bag provisions if the PBAC has recommended under subsection 101(4AACA) that the drug be made available only under one or more of the prescriber bag provisions.

Paragraph 85(7A) provides that the Minister may determine that a particular pharmaceutical benefit may only be supplied under one or more of the prescriber bag provisions.

Variation and revocation

Unless there is an express power to revoke or vary PB 71 of 2012 cited in this Instrument and explanatory statement, subsection 33(3) of the *Acts Interpretation Act 1901* is relied upon to revoke or vary PB 71 of 2012.

Subsection 101(4AAA) allows the Minister to, by legislative instrument, revoke or vary a subsection 85(2) declaration in relation to a drug or medicinal preparation. Advice from the Pharmaceutical Benefits Advisory Committee (PBAC) is required if the effect of the legislative instrument would be that a drug or medicinal preparation would cease to be a listed drug (subsection 101(4AAB)).

Changes to PB 71 of 2012 made by this instrument

Schedule 1 to this instrument provides for additions, deletions and changes to drugs, forms, brands, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities, section 100 only status and prescriber bag only status. These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of PBAC constitutes a formal and ongoing process of consultation. PBAC is an 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 appointed following nomination by prescribed organisations and associations 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 PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

General

A provision by provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 October 2013.

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2013 (No. 11)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 11)* and may also be cited as PB 61 of 2013.

Section 2 Commencement

This section provides that this Instrument commences on 1 October 2013.

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

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

Schedule 1 Amendments

The amendments in Schedule 1 involve additions, deletions and changes to forms, brands, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities and section 100 only status. These changes are summarised below.

SUMMARY OF CHANGES

Brands Added

Candesartan	Tablet containing candesartan cilexetil 4 mg (Candesartan RBX) Tablet containing candesartan cilexetil 8 mg (Candesartan RBX) Tablet containing candesartan cilexetil 16 mg (Candesartan RBX) Tablet containing candesartan cilexetil 32 mg (Candesartan RBX)
Candesartan with Hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg (Candesartan HCTZ RBX 16/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (Candesartan HCTZ RBX 32/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (Candesartan HCTZ RBX 32/25)
Gabapentin	Capsule 100 mg (Gabapentin Aspen 100) Capsule 300 mg (Gabapentin Aspen 300) Capsule 400 mg (Gabapentin Aspen 400)
Isotretinoin	Capsule 10 mg (Isotretinoin SCP 10) Capsule 20 mg (Isotretinoin SCP 20)
Meloxicam	Capsule 7.5 mg (Meloxicam Sandoz) Capsule 15 mg (Meloxicam Sandoz)
Montelukast	Tablet, chewable, 4 mg (as sodium) (Auro-Montelukast Tabs 4) Tablet, chewable, 5 mg (as sodium) (Auro-Montelukast Tabs 5)
Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated) (Rabeprazole-DRLA) Tablet containing rabeprazole sodium 20 mg (enteric coated) (Rabeprazole-DRLA)

Roxithromycin	Tablet 150 mg (Roxithromycin SCP 150) Tablet 300 mg (Roxithromycin SCP 300)
Sumatriptan	Tablet 50 mg (as succinate) (Sumatriptan Sandoz)
Terbinafine	Tablet 250 mg (as hydrochloride) (Terbinafine GH)
Tramadol	Capsule containing tramadol hydrochloride 50 mg (Tramadol SCP)
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride) (Venlafaxine SR SCP 75) Capsule (modified release) 150 mg (as hydrochloride) (Venlafaxine SR SCP 150)
Zolmitriptan	Tablet 2.5 mg (Zoltrip)

Brands Deleted

Carbomer	Eye gel 2 mg per g, 10 g (GelTears)
Cephazolin	Powder for injection 500 mg (as sodium) (Hospira Pty Limited)
Doxycycline	Tablet 50 mg (as hydrochloride) (Vibra-Tabs)
Gabapentin	Capsule 100 mg (DBL Gabapentin) Capsule 300 mg (DBL Gabapentin) Capsule 400 mg (DBL Gabapentin)
Gemcitabine	Powder for I.V. infusion 200 mg (as hydrochloride) (AS-Gemcitabine) Powder for I.V. infusion 1 g (as hydrochloride) (AS-Gemcitabine) Powder for I.V. infusion 2 g (as hydrochloride) (AS-Gemcitabine)
Oxaliplatin	Solution concentrate for I.V. infusion 50 mg in 10 mL (AS-Oxaliplatin) Solution concentrate for I.V. infusion 100 mg in 20 mL (AS-Oxaliplatin) Solution concentrate for I.V. infusion 200 mg in 40 mL (AS-Oxaliplatin)
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL (GN-Paclitaxel) Solution concentrate for I.V. infusion 100 mg in 16.7 mL (GN-Paclitaxel) Solution concentrate for I.V. infusion 300 mg in 50 mL (GN-Paclitaxel)
Pamidronic Acid	Concentrated injection containing disodium pamidronate 30 mg in 10 mL (Pamidronate Strides) Concentrated injection containing disodium pamidronate 90 mg in 10 mL (Pamidronate Strides)
Quinapril	Tablet 5 mg (as hydrochloride) (Quinapril Sandoz) Tablet 20 mg (as hydrochloride) (Quinapril Sandoz)
Rabeprazole	Tablet containing rabeprazole sodium 20 mg (enteric coated) (Rabeprazole-GA)
Vinorelbine	Solution for I.V. infusion 10 mg (as tartrate) in 1 mL (AS-Vinorelbine) Solution for I.V. infusion 50 mg (as tartrate) in 5 mL (AS-Vinorelbine)

Alteration of Brand Name

Listed Drug	Form	Brand Name
Paraffin	Pack containing 2 tubes eye ointment, compound, containing white soft paraffin with liquid paraffin, 3.5 g	*From:* Lacri-Lube *To:* Refresh Night Time

Alteration of Responsible Person

Listed Drug	Form	Brand	Responsible Person
Timolol	Eye gel 1 mg (as maleate) per g, 5 g	Nyogel	*From:* Novartis Pharmaceuticals Australia Pty Limited (NV) *To:* Aspen Pharmacare Australia Pty Limited (AS)

The following brands previously listed with the Responsible Person Ascent Pharma Pty Ltd (GM) are now listed with the Responsible Person Actavis Pty Ltd (GN):

Aciclovir	Tablet 200 mg (Lovir)
Alendronic Acid	Tablet 70 mg (as alendronate sodium) (Alendronate-GA)
Alendronic acid with colecalciferol	Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol (Dronalen Plus)
Alprazolam	Tablet 1 mg (Ralozam) Tablet 2 mg (Ralozam)
Amoxycillin	Capsule 250 mg (as trihydrate) (Amoxycillin-GA) Capsule 500 mg (as trihydrate) (Amoxycillin-GA) Powder for oral suspension 125 mg (as trihydrate) per 5 mL, 100 mL (Bgramin) Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (Bgramin)
Amoxycillin with Clavulanic Acid	Tablet containing 500 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (GA-Amclav 500/125) Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (GA-Amclav Forte 875/125) Powder for oral suspension containing 125 mg amoxycillin (as trihydrate) with 31.25 mg clavulanic acid (as potassium clavulanate) per 5 mL, 75 mL (GA-Amclav 125/31.25) Powder for oral suspension containing 400 mg amoxycillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 60 mL (GA-Amclav Forte 400/57)
Anastrozole	Tablet 1 mg (Anastrozole-GA)
Atorvastatin	Tablet 10 mg (as calcium) (Atorvachol) Tablet 20 mg (as calcium) (Atorvachol) Tablet 40 mg (as calcium) (Atorvachol) Tablet 80 mg (as calcium) (Atorvachol)
Azathioprine	Tablet 50 mg (Azamun)
Azithromycin	Tablet 500 mg (as dihydrate) (Zitrocin)
Bicalutamide	Tablet 50 mg (Bicalutamide-GA)
Bupropion	Tablet containing bupropion hydrochloride 150 mg (sustained release) (Prexaton)
Cabergoline	Tablet 500 micrograms (Dostan) Tablet 1 mg (Cobasol) Tablet 2 mg (Cobasol)
Candesartan	Tablet containing candesartan cilexetil 4 mg (Candesartan-GA) Tablet containing candesartan cilexetil 8 mg (Candesartan-GA) Tablet containing candesartan cilexetil 16 mg (Candesartan-GA) Tablet containing candesartan cilexetil 32 mg (Candesartan-GA)
Candesartan with Hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg (Candesartan HCTZ-GA 16/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg(Candesartan HCTZ-GA 32/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (Candesartan HCTZ-GA 32/25)

Carvedilol	Tablet 3.125 mg (GN-Carvedilol) Tablet 6.25 mg (GN-Carvedilol) Tablet 12.5 mg (GN-Carvedilol) Tablet 25 mg (GN-Carvedilol)
Cephalexin	Capsule 250 mg (anhydrous) (Cilex) Capsule 500 mg (anhydrous) (Cilex) Granules for oral suspension 125 mg per 5 mL, 100 mL (Cilex) Granules for oral suspension 250 mg per 5 mL, 100 mL (Cilex)
Ciprofloxacin	Tablet 500 mg (as hydrochloride) (Ciprofloxacin-GA) Tablet 750 mg (as hydrochloride) (Ciprofloxacin-GA)
Clarithromycin	Tablet 250 mg (Clarac)
Clopidogrel	Tablet 75 mg (as besilate) (Clopidogrel-GA)
Coal tar – Prepared	Gel 10 mg per g, 100 mL (Exorex)
Cromoglycic acid	Capsule containing powder for oral inhalation containing sodium cromoglycate 20 mg (for use in Intal Spinhaler or Intal Halermatic) (Intal Spincaps)
Cyproterone	Tablet containing cyproterone acetate 50 mg (Procur) Tablet containing cyproterone acetate 100 mg (Procur 100)
Diazepam	Tablet 5 mg (Diazepam-GA)
Diclofenac	Tablet (enteric coated) containing diclofenac sodium 25 mg (Diclofenac-GA) Tablet (enteric coated) containing diclofenac sodium 50 mg (Diclofenac-GA)
Diltiazem	Tablet containing diltiazem hydrochloride 60 mg (Dilzem 60 mg)
Donepezil	Tablet containing donepezil hydrochloride 5 mg (Donepezil-GA) Tablet containing donepezil hydrochloride 10 mg (Donepezil-GA)
Doxycycline	Tablet 50 mg (as hydrochloride) (Doxy-50) Tablet 100 mg (as hydrochloride) (Doxy-100)
Duloxetine	Capsule 30 mg (as hydrochloride) (Drulox) Capsule 60 mg (as hydrochloride) (Drulox)
Electrolyte Replacement, Oral	Oral rehydration salts containing glucose 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10 (restore O.R.S.)
Enalapril	Tablet containing enalapril maleate 5 mg (Enalapril-GA) Tablet containing enalapril maleate 10 mg (Enalapril-GA) Tablet containing enalapril maleate 20 mg (Enalapril-GA)
Exemestane	Tablet 25 mg (Exemestane-GA)
Famciclovir	Tablet 125 mg (Famciclovir-GA) Tablet 250 mg (Famciclovir-GA) Tablet 500 mg mg (Famciclovir-GA)
Famotidine	Tablet 20 mg (Pepzan) Tablet 40 mg (Pepzan)
Fentanyl	Transdermal patch 2.063 mg (Dutran 12) Transdermal patch 4.125 mg (Dutran 25) Transdermal patch 8.25 mg (Dutran 50) Transdermal patch 12.375 mg (Dutran 75) Transdermal patch 6.5 mg (Dutran 100)
Fluoxetine	Capsule 20 mg (as hydrochloride) (Fluoxetine-GA)
Fluvoxamine	Tablet containing fluvoxamine maleate 50 mg (Fluvoxamine GA) Tablet containing fluvoxamine maleate 100 mg (Fluvoxamine GA)
Fosinopril with Hydrochlorothiazide	Tablet containing fosinopril sodium 10 mg with hydrochlorothiazide 12.5 mg (Fosinopril/HCTZ-GA 10/12/5) Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg (Fosinopril/HCTZ-GA 20/12/5)
Frusemide	Tablet 20 mg (Frusid)

Glimepiride	Tablet 1 mg (Glimepiride GA 1) Tablet 2 mg (Glimepiride GA 2) Tablet 3 mg (Glimepiride GA 3) Tablet 4 mg (Glimepiride GA 4)
Hydroxychloroquine	Tablet containing hydroxychloroquine sulfate 200 mg (Hydroxychloroquine Actavis)
Indapamide	Tablet containing indapamide hemihydrate 2.5 mg (Indapamide-GA)
Irbesartan	Tablet 75 mg (Irbesartan-GA) Tablet 150 mg (Irbesartan-GA) Tablet 300 mg (Irbesartan-GA)
Irbesartan with Hydrochlorothiazide	Tablet 150 mg-12.5 mg (Irbesartan HCTZ-GA 150/12.5) Tablet 300 mg-12.5 mg (Irbesartan HCTZ-GA 300/12.5) Tablet 300 mg-25 mg (Irbesartan HCTZ-GA 300/25)
Isosorbide mononitrate	Tablet 60 mg (sustained release) (Imtrate 60 mg)
Isotretinoin	Capsule 10 mg (Oratane) Capsule 20 mg (Oratane) Capsule 40 mg (Oratane)
Lactulose	Solution BP 3.34 g per 5 mL, 500 mL (Lac-Dol)
Leflunomide	Tablet 10 mg (Leflunomide-GA) Tablet 20 mg (Leflunomide-GA)
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg (Lercadip) Tablet containing lercanidipine hydrochloride 20 mg (Lercadip)
Letrozole	Tablet 2.5 mg (Letrozole-GA)
Levetiracetam	Tablet 250 mg (Kepcet) Tablet 500 mg (Kepcet) Tablet 1 g (Kepcet)
Macrogol 3350	Sachets containing powder for oral solution 13.125 g with electrolytes, 30 (LaxaCon)
Meloxicam	Tablet 7.5 mg (Meloxicam-GA) Tablet 15 mg (Meloxicam-GA) Capsule 7.5 mg (Melox 7.5) Capsule 15 mg (Melox 15)
Metformin	Tablet containing metformin hydrochloride 500 mg (Metformin-GA) Tablet containing metformin hydrochloride 850 mg (Metformin-GA) Tablet containing metformin hydrochloride 1 g (Metformin-GA)
Mirtazapine	Tablet 45 mg (Mirtazapine-GA)
Moclobemide	Tablet 150 mg (Clobemix) Tablet 300 mg (Clobemix)
Montelukast	Tablet, chewable, 4 mg (as sodium) ((Montair 4) Tablet, chewable, 5 mg (as sodium) (Montair 5)
Norfloxacin	Tablet 400 mg (Norfloxacin-GA)
Olanzapine	Tablet 2.5 mg (Olanzapine-GA) Tablet 5 mg (Olanzapine-GA) Tablet 7.5 mg (Olanzapine-GA) Tablet 10 mg (Olanzapine-GA) Tablet 5 mg (orally disintegrating) (Olanzapine-GA ODT) Tablet 10 mg (orally disintegrating) (Olanzapine-GA ODT)
Omeprazole	Tablet 20 mg (Omeprazole-GA) Capsule 20 mg (Omepro-GA)
Oxybutynin	Transdermal patches 36 mg, 8 (Oxytrol)
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate) (Pantoprazole-GA)
Paracetamol	Tablet 500 mg (Febridol)
Phenoxymethylpenicillin	Capsule 250 mg phenoxymethylpenicillin (as potassium) (Cilopen VK) Capsule 500 mg phenoxymethylpenicillin (as potassium) (Cilopen VK)

Pioglitazone	Tablet 15 mg (as hydrochloride) (Pioglitazone-GA) Tablet 30 mg (as hydrochloride) (Pioglitazone-GA) Tablet 45 mg (as hydrochloride) (Pioglitazone-GA)
Pravastatin	Tablet containing pravastatin sodium 10 mg (Pravastatin-GA 10) Tablet containing pravastatin sodium 20 mg (Pravastatin-GA 20) Tablet containing pravastatin sodium 40 mg (Pravastatin-GA 40) Tablet containing pravastatin sodium 80 mg (Pravastatin-GA 80)
Prochlorperazine	Tablet containing prochlorperazine maleate 5 mg (Prochlorperazine-GA)
Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated) (Rabeprazole-GA)
Ramipril	Capsule 1.25 mg (Ramipril-GA) Capsule 2.5 mg (Ramipril-GA) Capsule 5 mg (Ramipril-GA) Capsule 10 mg (Ramipril-GA)
Ranitidine	Tablet 150 mg (as hydrochloride) (Ranoxyl) Tablet 300 mg (as hydrochloride) (Ranoxyl)
Risedronic acid	Tablet containing risedronate sodium 35 mg (Risedronate-GA)
Risperidone	Tablet 0.5 mg (Risperidone-GA) Tablet 1 mg (Risperidone-GA) Tablet 2 mg(Risperidone-GA) Tablet 3 mg (Risperidone-GA) Tablet 4 mg (Risperidone-GA)
Roxithromycin	Tablet 150 mg (Roxithromycin-GA) Tablet 300 mg (Roxithromycin-GA)
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 (Salbutamol-GA) Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 (Salbutamol-GA)
Sumatriptan	Tablet 50 mg (as succinate) (Sumitriptan-GA)
Tamoxifen	Tablet 20 mg (as citrate) (Tamoxen 20 mg)
Testosterone	Transdermal patches 12.2 mg, 60 (Androderm) Transdermal patches 24.3 mg, 30 (Androderm)
Topiramate	Tablet 25 mg (Topiramate-GA) Tablet 50 mg (Topiramate-GA) Tablet 100 mg (Topiramate-GA) Tablet 200 mg (Topiramate-GA)
Tramadol	Capsule containing tramadol hydrochloride 50 mg (GA Tramadol 50mg) Tablet (sustained release) containing tramadol hydrochloride 100 mg (GA Tramadol SR 100mg) Tablet (sustained release) containing tramadol hydrochloride 150 mg (GA Tramadol SR 150mg) Tablet (sustained release) containing tramadol hydrochloride 200 mg (GA Tramadol SR 200mg)
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride) (Venlexor XR) Capsule (modified release) 150 mg (as hydrochloride) (Venlexor XR)

The following brands previously listed with the Responsible Person Ascent Pharma Pty Ltd (GM) are now listed with the Responsible Person Actavis Pty Ltd (UA):

Amlodipine	Tablet 5 mg (as besylate) (Amlodipine-GA) Tablet 10 mg (as besylate) (Amlodipine-GA)
Calcitriol	Capsule 0.25 microgram (Calcitriol-GA)
Citalopram	Tablet 20 mg (as hydrobromide) (Ciazil)
Escitalopram	Tablet 10 mg (as oxalate) (Esipram) Tablet 20 mg (as oxalate) (Esipram)
Frusemide	Tablet 40 mg (Frusid)
Gabapentin	Capsule 300 mg (Gabapentin-GA)

Gemfibrozil	Tablet 600 mg (Gemfibrozil-GA)
Mirtazapine	Tablet 30 mg (Mirtazapine-DP)
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) (Pantoprazole-GA)
Perindopril	Tablet containing perindopril erbumine 2 mg (Perindopril-GA) Tablet containing perindopril erbumine 4 mg (Perindopril-GA) Tablet containing perindopril erbumine 8 mg (Perindopril-GA)
Quinapril	Tablet 20 mg (as hydrochloride) (Quinapril-GA)
Sertraline	Tablet 50 mg (as hydrochloride) (Sertraline-GA) Tablet 100 mg (as hydrochloride) (Sertraline-GA)
Simvastatin	Tablet 10 mg (Simvastatin-DP) Tablet 20 mg (Simvastatin-DP) Tablet 40 mg(Simvastatin-DP) Tablet 80 mg (Simvastatin-DP)
Terbinafine	Tablet 250 mg (as hydrochloride) (Terbinafine-GA)
Valaciclovir	Tablet 500 mg (as hydrochloride) (Zelitrex)

The following brands previously listed with the Responsible Person Ascent Pharma Pty Ltd (GM) are now listed with the Responsible Person Actavis Pty Ltd (VN):

Quetiapine	Tablet 25 mg (as fumarate) (Quipine) Tablet 100 mg (as fumarate) (Quipine) Tablet 200 mg (as fumarate) (Quipine) Tablet 300 mg (as fumarate) (Quipine)

The following brands previously listed with the Responsible Person Willow Pharmaceuticals Pty Ltd (WQ) are now listed with the Responsible Person Actavis Pty Ltd (GN):

Ampicillin	Powder for injection 500 mg (as sodium) (Ibimycin) Powder for injection 1 g (as sodium) (Ibimycin)
Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg (Biso 2.5) Tablet containing bisoprolol fumarate 5 mg (Biso 5) Tablet containing bisoprolol fumarate 10 mg (Biso 10)
Bleomycin	Powder for injection containing bleomycin sulfate 15,000 I.U. (Bleo 15K)
Carboplatin	Solution for I.V. injection 50 mg in 5 mL (Carbaccord) Solution for I.V. injection 150 mg in 15 mL (Carbaccord) Solution for I.V. injection 450 mg in 45 mL (Carbaccord)
Doxorubicin	Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 10 mg in 5 mL single dose vial (Accord Doxorubicin) Solution for I.V. injection or intravesical administration containing doxorubicin hydrochloride 200 mg in 100 mL single dose vial (Accord Doxorubicin)
Epirubicin	Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL (Epiccord) Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL (Epiccord) Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL (Eppicord) Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL (Epiccord)
Flucloxacillin	Powder for injection 500 mg (as sodium) (Flubiclox) Powder for injection 1 g (as sodium) (Flubiclox)
Fludarabine	Powder for I.V. injection containing fludarabine phosphate 50 mg (Farine)

Gemcitabine	Powder for I.V. infusion 200 mg (as hydrochloride) (Gemaccord) Powder for I.V. infusion 200 mg (as hydrochloride) (Gemcitabine Actavis) Powder for I.V. infusion 1 g (as hydrochloride) (Gemaccord) Powder for I.V. infusion 1 g (as hydrochloride) (Gemcitabine Actavis) Powder for I.V. infusion 1 g (as hydrochloride) (Gemplan) Powder for I.V. infusion 2 g (as hydrochloride) (Gemcitabine Actavis 2000) Powder for I.V. infusion 2 g (as hydrochloride) (Gemplan)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL (Irinoccord) I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL (Tecan) I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL (Irinoccord) I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL (Tecan) I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL (Tecan)
Methotrexate	Injection 50 mg in 2 mL vial (Methaccord) Solution concentrate for I.V. infusion 1000 mg in 10 mL vial (Methaccord)
Ondansetron	Tablet (orally disintegrating) 4 mg (Onsetron ODT 4) Tablet (orally disintegrating) 8 mg (Onsetron ODT 8)
Oxaliplatin	Solution concentrate for I.V. infusion 50 mg in 10 mL (Oxaliccord) Solution concentrate for I.V. infusion 100 mg in 20 mL (Oxaliccord) Powder for I.V. infusion 50 mg (Xalox) Powder for I.V. infusion 100 mg (Xalox)
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL (Plaxel) Solution concentrate for I.V. infusion 100 mg in 16.7 mL (Plaxel) Solution concentrate for I.V. infusion 150 mg in 25 mL (Plaxel) Solution concentrate for I.V. infusion 300 mg in 50 mL (Plaxel)
Rosuvastatin	Tablet 5 mg (as calcium) (Rosuvastatin Actavis 5) Tablet 10 mg (as calcium) (Rosuvastatin Actavis 10) Tablet 20 mg (as calcium) (Rosuvastatin Actavis 20) Tablet 40 mg (as calcium) (Rosuvastatin Actavis 40)
Temozolomide	Capsule 5 mg (Astromide) Capsule 20 mg (Astromide) Capsule 100 mg (Astromide) Capsule 140 mg (Astromide) Capsule 180 mg (Astromide) Capsule 250 mg (Astromide)
Vancomycin	Powder for injection 500 mg (500,000 I.U.) (as hydrochloride) (Vycin IV) Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride) (Vycin IV)

The following brands previously listed with the Responsible Person Willow Pharmaceuticals Pty Ltd (WQ) are now listed with the Responsible Person Actavis Pty Ltd (UA):

Anastrozole	Tablet 1 mg (Anzole)
Letrozole	Tablet 2.5 mg (Lezole)
Quetiapine	Tablet 25 mg (as fumarate) (Quetiaccord) Tablet 100 mg (as fumarate) (Quetiaccord) Tablet 200 mg (as fumarate) (Quetiaccord) Tablet 300 mg (as fumarate) (Quetiaccord)

Alteration of Name of Responsible Person (entity name only)

From: Ascent Pharmaceuticals Limited [GN] *To:* Actavis Pty Ltd [GN]

Addition of Responsible Person Code

Actavis Pty Ltd [UA]

Actavis Pty Ltd [VN]

Deletion of Responsible Person Code

Ascent Pharma Pty Ltd [GM]

Willow Pharmaceuticals Pty Ltd [WQ]

Alteration of Circumstances

Listed Drug	Alteration
Zolmitriptan	Circumstances amended, removing some restrictions previously applied for the prescribing of this drug

Statement of Compatibility with Human Rights

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

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

(PB 61 of 2013)

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

The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 11)* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* which determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, maximum quantities, numbers of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

Schedule 1 to this instrument provides for additions, deletions and changes to drugs, forms, brands, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities, section 100 only status and prescriber bag only status.

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

Conclusion

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

Felicity McNeill
First Assistant Secretary
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Department of Health and Ageing