EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2014 (No. 6)

PB 45 of 2014

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 July 2014.

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 2014 (No. 6)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 6)* and may also be cited as PB 45 of 2014.

Section 2 Commencement

This section provides that this Instrument commences on 1 July 2014.

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

Forms Added

Bimatoprost with timolol	Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30

Forms Deleted

Nicotine	Transdermal patch 24.9 mg

Brands Added

Candesartan with Hydrochlorothiazide	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (Adesan HCT 32/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (Adesan HCT 32/25)
Cefepime	Powder for injection 1 g (as hydrochloride) (Cefepime Alphapharm) Powder for injection 2 g (as hydrochloride) (Cefepime Alphapharm)
Clarithromycin	Tablet 250 mg (Clarihexal)
Lamotrigine	Tablet 5 mg (Lamotrigine Aspen 5)
Latanoprost	Eye drops 50 micrograms per mL, 2.5 mL (Latanoprost GH)
Latanoprost with timolol	Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL (APO-Latanoprost/Timolol 0.05/5)
Memantine	Tablet containing memantine hydrochloride 20 mg (APO-Memantine)
Mirtazapine	Tablet 15 mg (orally disintegrating) (Mirtazapine Sandoz ODT 15) Tablet 30 mg (orally disintegrating) (Mirtazapine Sandoz ODT 30) Tablet 45 mg (orally disintegrating) (Mirtazapine Sandoz ODT 45)

Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) (Pantoprazole Actavis)
Rosuvastatin	Tablet 5 mg (as calcium) (Rosuvastatin-DRLA) Tablet 10 mg (as calcium) (Rosuvastatin-DRLA) Tablet 20 mg (as calcium) (Rosuvastatin-DRLA) Tablet 40 mg (as calcium) (Rosuvastatin-DRLA)
Sumatriptan	Tablet 50 mg (as succinate) (Sumatran)
Telmisartan with amlodipine	Tablet 40 mg-5 mg (as besylate) (Pritor/Amlodipine) Tablet 40 mg-10 mg (as besylate) (Pritor/Amlodipine) Tablet 80 mg-5 mg (as besylate) (Pritor/Amlodipine) Tablet 80 mg-10 mg (as besylate) (Pritor/Amlodipine)

Brands Deleted

Ciprofloxacin	Tablet 250 mg (as hydrochloride) (Cifran)
Diltiazem	Tablet containing diltiazem hydrochloride 60 mg (Coras)
Docetaxel	Solution concentrate for I.V. infusion 20 mg in 1 mL (Oncotaxel 20)
Doxycycline	Tablet 50 mg (as monohydrate) (Doxyhexal) Tablet 100 mg (as monohydrate) (Doxyhexal)
Fosinopril with Hydrochlorothiazide	Tablet containing fosinopril sodium 10 mg with hydrochlorothiazide 12.5 mg (Hyforil) Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg (Hyforil)
Glucose	I.V. infusion 278 mmol (anhydrous) per L, 1 L (Fresenius Kabi Australia Pty Limited)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL (Irinotecan Actavis)
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)
Simvastatin	Tablet 10 mg (Simvastatin-Spirit 10) Tablet 20 mg (Simvastatin-Spirit 20) Tablet 40 mg (Simvastatin-Spirit 40) Tablet 80 mg (Simvastatin-Spirit 80)
Sodium Chloride	I.V. infusion 154 mmol per L. 1 L (Fresenius Kabi Australia Pty Limited)
Sodium Lactate Compound	I.V. infusion containing approximately 131 mmol sodium (as lactate and chloride), 5 mmol potassium (as chloride), 2 mmol calcium (as chloride), 29 mmol bicarbonate (as lactate) and 111 mmol chloride per L, 1 L (Fresenius Kabi Australia Pty Limited)
Tramadol	Capsule containing tramadol hydrochloride 50 mg (Lodam 50)

Alteration of Brand Name

Listed Drug	**Form**	**Brand Name**
Atorvastatin and ezetimibe	Pack containing 30 tablets atorvastatin 10 mg (as calcium) and 30 tablets ezetimibe 10 mg	*From:* Atozet Composite Pack 10mg + 10mg *To:* Atozet Composite Pack
	Pack containing 30 tablets atorvastatin 20 mg (as calcium) and 30 tablets ezetimibe 10 mg	*From:* Atozet Composite Pack 10mg + 20mg *To:* Atozet Composite Pack
	Pack containing 30 tablets atorvastatin 40 mg (as calcium) and 30 tablets ezetimibe 10 mg	*From:* Atozet Composite Pack 10mg + 40mg *To:* Atozet Composite Pack
	Pack containing 30 tablets atorvastatin 80 mg (as calcium) and 30 tablets ezetimibe 10 mg	*From:* Atozet Composite Pack 10mg + 80mg *To:* Atozet Composite Pack

Alteration of Responsible Person

Listed Drug	Form	Brand Name	Responsible Person
Acitretin	Capsule 10 mg Capsule 25 mg	Neotigason Neotigason	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
Clopidogrel	Tablet 75 mg (as besilate)	Clopidogrel Actavis	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
Diphenoxylate with Atropine	Tablet containing diphenoxylate hydrochloride 2.5 mg with atropine sulfate 25 micrograms	Lofenoxal	From: Biotech Pharmaceuticals Pty Ltd (HC) To: iNova Pharmaceuticals (Australia) Pty Limited (IA)
		Lomotil	From: Biotech Pharmaceuticals Pty Ltd (BI) To: iNova Pharmaceuticals (Australia) Pty Limited (IV)
Docetaxel	Solution concentrate for I.V. infusion 80 mg in 4 mL	Oncotaxel 80	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (GN)
	Solution concentrate for I.V. infusion 140 mg in 7 mL	Oncotaxel 140	
Epirubicin	Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL	Epirubicin Actavis 10	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
	Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL	Epirubicin Actavis 20	
	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL	Epirubicin Actavis 50	
	Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL	Epirubicin Actavis 200	
Fludarabine	Powder for I.V. injection containing fludarabine phosphate 50 mg	Fludarabine Actavis	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL	Irinotecan Actavis	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL	Irinotecan Actavis 500	
Lamotrigine	Tablet 25 mg Tablet 50 mg Tablet 100 mg Tablet 200 mg	Torlemo DT 25 Torlemo DT 50 Torlemo DT 100 Torlemo DT 200	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
Letrozole	Tablet 2.5 mg	Letrozole Actavis	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (VN)
Oxaliplatin	Powder for I.V. infusion 50 mg	Oxaliplatin Actavis	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
	Powder for I.V. infusion 100 mg	Oxaliplatin Actavis	

Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL	Paclitaxel Actavis	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
	Solution concentrate for I.V. infusion 100 mg in 16.7 mL	Paclitaxel Actavis	
	Solution concentrate for I.V. infusion 150 mg in 25 mL	Paclitaxel Actavis	
	Solution concentrate for I.V. infusion 300 mg in 50 mL	Paclitaxel Actavis	
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Torzole 20	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (VN)
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Torzole 40	
Pravastatin	Tablet containing pravastatin sodium 10 mg	Pravastatin Actavis 10	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (UA)
	Tablet containing pravastatin sodium 20 mg	Pravastatin Actavis 20	
	Tablet containing pravastatin sodium 40 mg	Pravastatin Actavis 40	
Quetiapine	Tablet 25 mg (as fumarate)	Quetiapine Actavis 25	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (VN)
	Tablet 100 mg (as fumarate)	Quetiapine Actavis 100	
	Tablet 200 mg (as fumarate)	Quetiapine Actavis 200	
	Tablet 300 mg (as fumarate)	Quetiapine Actavis 300	
Reteplase	Pack containing 2 vials powder for injection 10 units, 2 single use pre-filled syringes with solvent, 2 reconstitution spikes and 2 needles	Rapilysin 10 U	From: Actavis Australia Pty Ltd (TA) To: Actavis Pty Ltd (GN)

Alteration of Maximum Quantity and Number of Repeats

Listed Drug	Form	Brand	Max Qty	No. of Rpts
Octreotide	Injection (modified release) 10 mg (as acetate), vial and diluent syringe	Sandostatin LAR	*From:* 1 *To:* 2	*From:* 11 *To:* 5
	Injection (modified release) 20 mg (as acetate), vial and diluent syringe	Sandostatin LAR	*From:* 1 *To:* 2	*From:* 11 *To:* 5
	Injection (modified release) 30 mg (as acetate), vial and diluent syringe	Sandostatin LAR	*From:* 1 *To:* 2	*From:* 11 *To:* 5

Alteration of Number of Repeats

Listed Drug	Form	Brand	No. of Rpts
Lanreotide	Injection 60 mg (as acetate) in single dose pre-filled syringe	Somatuline Autogel	*From:* 11 *To:* 5
	Injection 90 mg (as acetate) in single dose pre-filled syringe	Somatuline Autogel	*From:* 11 *To:* 5
	Injection 120 mg (as acetate) in single dose pre-filled syringe	Somatuline Autogel	*From:* 11 *To:* 5

Addition of Responsible Person Code

iNova Pharmaceuticals (Australia) Pty Limited [IV]

Deletion of Responsible Person Code

Actavis Australia Pty Limited [TA]

Biotech Pharmaceuticals Pty Ltd [BI]

Biotech Pharmaceuticals Pty Ltd [HC]

Alteration of Circumstances

Listed Drug	Alteration
Ivermectin	Circumstances amended to extend availability for the treatment of crusted (norwegian) scabies and human sarcoptic scabies
Octreotide	Circumstances amended to replace sandostatin subcutaneous injections with octreotide immediate release injections for controlling symptoms

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 2014 (No. 6)

(PB 45 of 2014)

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 2014 (No. 6)* 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.

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