EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listing of Pharmaceutical Benefits)

Amendment Instrument 2012 (No. 6)

PB 44 of 2012

Purpose

The purpose of this legislative instrument, made under sections 84AF, 85, 85A, 88, and 101 of the *National Health Act 1953* (the Act) is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* (PB 108 of 2010) to make changes to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 108 of 2010 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 and numbers of repeats, and whether the pharmaceutical benefit is to be available only under special arrangements).

Authority

PB 108 of 2010 exercises numerous provisions 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)).

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).

Variation and revocation of subsection 85(2) declaration

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 108 of 2010 made by this instrument

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), and section 100 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, and agreement to final listing details.

Medical and pharmacy professional groups, key stakeholder groups representing oncologists and pharmacists, State and Territory health departments, as well as the Department of Human Services and the Medical Software Industry Association, were also consulted throughout the process of developing all legislative instruments under the Act necessary to implement the section 100 special arrangement for the Efficient Funding of Chemotherapy.

General

The Instrument commences on 1 August 2012.

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 2012 (No. 6)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2012 (No. 6)* and may also be cited as PB 44 of 2012.

Section 2 Commencement

This section provides that the Instrument commences on 1 August 2012.

Section 3 Amendment of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* (PB 108 of 2010)

This section provides that Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* (PB 108 of 2010).

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), and section 100 only status. These changes are summarised below.

SUMMARY OF CHANGES

Listed Drugs Added

Cabazitaxel

Icatibant

Mannitol

Rasagiline

Ticagrelor

Forms Added

Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine	Oral liquid 130 mL, 30 (MMA/PA cooler)
Amino acid formula with vitamins and minerals without phenylalanine	Sachets containing oral powder 34 g, 30 (PKU express 20)
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	Sachets containing oral powder 34 g, 30 (MSUD express 20)
Auranofin	Capsule 3 mg
Cefuroxime	Powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL
Triglycerides – medium chain, formula	Oral powder 400 g (Lipistart)

Forms Deleted

Oestradiol	Transdermal patches 2 mg, 8
Tipranavir	Oral liquid 100 mg per mL, 95 mL

Brands Added

Aspirin	Tablet 100 mg (Spren 100)
Atorvastatin	Tablet 10 mg (as calcium) (Atorvastatin SCP 10; STADA Atorvastatin) Tablet 20 mg (as calcium) (Atorvastatin SCP 20; STADA Atorvastatin) Tablet 40 mg (as calcium) (Atorvastatin SCP 40; STADA Atorvastatin) Tablet 80 mg (as calcium) (Atorvastatin SCP 80; STADA Atorvastatin)
Cefepime	Powder for injection 1 g (as hydrochloride) (with any determined brand of sodium chloride injection as the required solvent) (Cefepime Sandoz) Powder for injection 2 g (as hydrochloride) (with any determined brand of sodium chloride injection as the required solvent) (Cefepime Sandoz)
Clopidogrel	Tablet 75 mg (as besilate) (STADA Clopidogrel) Tablet 75 mg (as hydrogen sulfate) (Plavicor 75)
Cyproterone	Tablet containing cyproterone acetate 100 mg (Cyprocur 100)
Diltiazem	Capsule (controlled delivery) containing diltiazem hydrochloride 240 mg (Diltiazem Sandoz CD) Capsule (controlled delivery) containing diltiazem hydrochloride 360 mg (Diltiazem Sandoz CD)
Enalapril	Tablet containing enalapril maleate 5 mg (Enalapril-PS) Tablet containing enalapril maleate 10 mg (Enalapril-PS) Tablet containing enalapril maleate 20 mg (Enalapril-PS)
Galantamine	Capsule (prolonged release) 8 mg (as hydrobromide) (APO-Galantamine MR; Gamine XR) Capsule (prolonged release) 16 mg (as hydrobromide) (APO-Galantamine MR; Gamine XR) Capsule (prolonged release) 24 mg (as hydrobromide) (APO-Galantamine MR; Gamine XR)
Hydroxychloroquine	Tablet containing hydroxychloroquine sulphate 200 mg (APO-Hydroxychloroquine; Chem mart Hydroxychloroquine; Terry White Chemists Hydroxychloroquine)

Indapamide	Tablet containing indapamide hemihydrate 2.5 mg (Indapamide-PS)
Lamivudine	Tablet 150 mg (Lamivudine RBX) Tablet 300 mg (Lamivudine RBX)
Latanoprost	Eye drops 50 micrograms per mL, 2.5 mL (APO-Latanoprost; Chem mart Latanoprost; Latanoprost Pfizer; Latanoprost Sandoz; Terry White Chemists Latanoprost)
Latanoprost with Timolol	Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL (Latanocom)
Letrozole	Tablet 2.5 mg (Lezole)
Meloxicam	Capsule 7.5 mg (Melox 7.5) Capsule 15 mg (Melox 15) Tablet 7.5 mg (Meloxicam-PS) Tablet 15 mg (Meloxicam-PS)
Metformin	Tablet containing metformin hydrochloride 500 mg (Formet Aspen 500) Tablet containing metformin hydrochloride 850 mg (Formet Aspen 850)
Mirtazapine	Tablet 15 mg (orally disintegrating) (Remeron SolTab) Tablet 30 mg (orally disintegrating) (Remeron SolTab) Tablet 45 mg (orally disintegrating) (Remeron SolTab)
Norfloxacin	Tablet 400 mg (Norfloxacin-PS)
Olanzapine	Tablet 2.5 mg (as benzoate) (STADA Olanzapine) Tablet 5 mg (as benzoate) (STADA Olanzapine) Tablet 7.5 mg (as benzoate) (STADA Olanzapine) Tablet 10 mg (as benzoate) (STADA Olanzapine)
Omeprazole	Tablet 20 mg (Omeprazole-PS)
Pramipexole	Tablet containing pramipexole hydrochloride 125 micrograms (Simipex 0.125) Tablet containing pramipexole hydrochloride 250 micrograms (Simipex 0.25) Tablet containing pramipexole hydrochloride 1 mg (Simipex 1)
Pravastatin	Tablet containing pravastatin sodium 10 mg (Pravastatin-PS) Tablet containing pravastatin sodium 20 mg (Pravastatin-PS) Tablet containing pravastatin sodium 40 mg (Pravastatin-PS) Tablet containing pravastatin sodium 80 mg (Pravastatin-PS)
Quetiapine	Tablet 25 mg (as fumarate) (Quetiapine-Synthon; STADA Quetiapine) Tablet 100 mg (as fumarate) (Quetiapine-Synthon; STADA Quetiapine) Tablet 200 mg (as fumarate) (Quetiapine-Synthon; STADA Quetiapine) Tablet 300 mg (as fumarate) (Quetiapine-Synthon; STADA Quetiapine)
Ramipril	Capsule 1.25 mg (APO-Ramipril; Chem mart Ramipril; Terry White Chemists Ramipril) Capsule 2.5 mg (APO-Ramipril; Chem mart Ramipril; Terry White Chemists Ramipril) Capsule 5 mg (APO-Ramipril; Chem mart Ramipril; Terry White Chemists Ramipril)
Roxithromycin	Tablet 150 mg (Roxithromycin-PS) Tablet 300 mg (Roxithromycin-PS)
Simvastatin	Tablet 10 mg (Simvastatin-DRLA) Tablet 20 mg (Simvastatin-DRLA) Tablet 40 mg (Simvastatin-DRLA) Tablet 80 mg (Simvastatin-DRLA)
Sumatriptan	Tablet 50 mg (as succinate) (Sumagran Aspen 50)
Temozolomide	Capsule 5 mg (Orion Temozolomide) Capsule 20 mg (Orion Temozolomide) Capsule 100 mg (Orion Temozolomide) Capsule 140 mg (Orion Temozolomide) Capsule 250 mg (Orion Temozolomide)

Topotecan	Powder for I.V. infusion 4 mg (as hydrochloride) (Topotecan)

Brands Deleted

Cephalexin	Capsule 500 mg (anhydrous) (Cephabell)
Citalopram	Tablet 20 mg (as hydrobromide) (Citalobell)
Gliclazide	Tablet 80 mg (Mellihexal)
Risedronic Acid	Tablet containing risedronate sodium 35 mg (Actonel Once-a-Week)
Risedronic Acid and Calcium	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate) (Actonel Combi)
Simvastatin	Tablet 40 mg (Simvahexal)

Alteration of Form Description and Brand Name

Listed Drug	**Form**	**Brand Name**
Amino acid formula with vitamins and minerals without lysine and low in tryptophan	*From:* Sachets containing oral powder 25 g, 30 (GA express) *To:* Sachets containing oral powder 25 g, 30 (GA express 15)	*From:* GA express *To:* GA express 15
Amino acid formula with vitamins and minerals without methionine	*From:* Sachets containing oral powder 25 g, 30 (HCU express) *To:* Sachets containing oral powder 25 g, 30 (HCU express 15)	*From:* HCU express *To:* HCU express 15
Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine	*From:* Sachets containing oral powder 25 g, 30 (MMA/PA express) *To:* Sachets containing oral powder 25 g, 30 (MMA/PA express 15)	*From:* MMA/PA express *To:* MMA/PA express 15
Amino acid formula with vitamins and minerals without phenylalanine	*From:* Sachets containing oral powder 25 g, 30 (PKU Express) *To:* Sachets containing oral powder 25 g, 30 (PKU express 15)	*From:* PKU Express *To:* PKU express 15
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine	*From:* Sachets containing oral powder 25 g, 30 (TYR Express) *To:* Sachets containing oral powder 25 g, 30 (TYR express 15)	*From:* TYR Express *To:* TYR express 15
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	*From:* Sachets containing oral powder 25 g, 30 (MSUD Express) *To:* Sachets containing oral powder 25 g, 30 (MSUD express 15)	*From:* MSUD Express *To:* MSUD express 15

Alteration of Brand and Responsible Person

Listed Drug	Form	Brand	Responsible Person Code
Ceftriaxone	Powder for injection 1 g	*From:* Max Pharma Pty Ltd *To:* Max Pharma Ceftriaxone	*From:* Max Pharma Pty Ltd (XF) *To:* Generic Health Pty Ltd (GQ)

Alteration of Responsible Person

Listed Drug	Form	Brand	Responsible Person
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	Humira	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Injection 40 mg in 0.8 mL pre-filled pen	Humira	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Injection 40 mg in 0.8 mL pre-filled syringe	Humira	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Injection 40 mg in 0.8 mL pre-filled pen, 6	Humira	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Injection 40 mg in 0.8 mL pre-filled syringe, 6	Humira	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
Alendronic Acid	Tablet 70 mg (as alendronate sodium)	Alendrobell 70 mg	*From:* Bellwether Pharma Ltd (BF) *To:* Generic Health Pty Ltd (GQ)
Ciprofloxacin	Tablet 500 mg (as hydrochloride)	Ciprofloxacin-BW	*From:* Bellwether Pharma Ltd (BF) *To:* Generic Health Pty Ltd (GQ)
	Tablet 750 mg (as hydrochloride)	Ciprofloxacin-BW	*From:* Bellwether Pharma Ltd (BF) *To:* Generic Health Pty Ltd (GQ)
Leuprorelin	I.M. injection (modified release), powder for injection containing leuprorelin acetate 7.5 mg with diluent in pre-filled dual-chamber syringe	Lucrin Depot 7.5mg PDS	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	I.M. injection (modified release), powder for injection containing leuprorelin acetate 22.5 mg with diluent in pre-filled dual-chamber syringe	Lucrin Depot 3 Month PDS	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	I.M. injection (modified release), powder for injection containing leuprorelin acetate 30 mg with diluent in pre-filled dual-chamber syringe	Lucrin Depot 4 Month PDS	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)

Levodopa with Carbidopa	Intestinal gel 20 mg-5 mg per mL, 100 mL	Duodopa	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
Lopinavir with Ritonavir	Tablet 100 mg-25 mg	Kaletra	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Tablet 200 mg-50 mg	Kaletra	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Oral liquid 400 mg-100 mg per 5 mL, 60 mL	Kaletra	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
Meloxicam	Tablet 7.5 mg	Meloxibell	*From:* Bellwether Pharma Ltd (BF) *To:* Generic Health Pty Ltd (GQ)
	Tablet 15 mg	Meloxibell	*From:* Bellwether Pharma Ltd (BF) *To:* Generic Health Pty Ltd (GQ)
Octreotide	Injection 50 micrograms (as acetate) in 1 mL	Octreotide MaxRx	*From:* Max Pharma Pty Ltd (XF) *To:* Generic Health Pty Ltd (GQ)
	Injection 100 micrograms (as acetate) in 1 mL	Octreotide MaxRx	*From:* Max Pharma Pty Ltd (XF) *To:* Generic Health Pty Ltd (GQ)
	Injection 500 micrograms (as acetate) in 1 mL	Octreotide MaxRx	*From:* Max Pharma Pty Ltd (XF) *To:* Generic Health Pty Ltd (GQ)
Ritonavir	Tablet 100 mg	Norvir	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)
	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL	Norvir	*From:* Abbott Australasia Pty Ltd (AB) *To:* AbbVie Pty Ltd (VE)

Alteration of Responsible Person Code (no change to Responsible Person)

Listed Drug	Form	Brand	Responsible Person Code
Diltiazem	Capsule (controlled delivery) containing diltiazem hydrochloride 240 mg	Diltahexal CD	*From:* SZ *To:* HX
	Capsule (controlled delivery) containing diltiazem hydrochloride 360 mg	Diltahexal CD	*From:* SZ *To:* HX

Alteration of Maximum Quantity

Listed Drug	Form	Max Quantity
Morphine	Capsule containing morphine sulfate 10 mg (containing sustained release pellets)	*From:* 20 *To:* 28
	Capsule containing morphine sulfate 20 mg (containing sustained release pellets)	*From:* 20 *To:* 28

Capsule containing morphine sulfate 50 mg (containing sustained release pellets)	*From:* 20 *To:* 28
Capsule containing morphine sulfate 100 mg (containing sustained release pellets)	*From:* 20 *To:* 28

Addition of Responsible Person Code

TD [STADA Pharmaceuticals Australia Pty Limited]

VE [AbbVie Pty Ltd]

XA [Pharmaxis Ltd]

Deletion of Responsible Person Code

BF [Bellwether Pharma Ltd]

XF [Max Pharma Pty Ltd]

Alteration of Circumstances

Listed Drug	**Alteration**
Denosumab	Circumstances amended relating to treatment of osteoporosis in women aged 70 years or over
Docetaxel	Circumstances amended relating to the treatment of androgen independent (castration resistant) metastatic carcinoma of the prostate
Etanercept	Circumstances amended to include treatment of chronic plaque psoriasis in patients under 18 years of age

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 2012 (No. 6)

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 2012 (No. 6)* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* 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, and whether the pharmaceutical benefit is to be available only under special arrangements).

Human rights implications

This legislative instrument engages Article 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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