EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listing of Pharmaceutical Benefits)

Amendment Instrument 2012 (No. 8)

PB 93 of 2012

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, and whether the pharmaceutical benefit is to be available only under special arrangements).

Authority

PB 71 of 2012 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)). 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).

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 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 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

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

This Instrument commences on 1 December 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. 8)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2012 (No. 8)* and may also be cited as PB 93 of 2012.

Section 2 Commencement

This section provides that this Instrument commences on 1 December 2012.

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

Listed Drugs Added

Aflibercept

Hyaluronic acid

Listed Drug Deleted

Neomycin with Bacitracin

Forms Added

Atenolol	Oral solution 50 mg in 10 mL, 300 mL
Hydroxocobalamin	Injection 1 mg (as acetate) in 1 mL
Naloxone	Injection containing naloxone hydrochloride 400 micrograms in 1 mL pre-filled syringe
Naproxen	Oral suspension 125 mg per 5 mL, 474 mL
Paraffin	Eye ointment, compound, containing liquid paraffin, light liquid paraffin, wool fat, white soft paraffin and retinyl palmitate, 5g
Rivaroxaban	Tablet 15 mg Tablet 20 mg

Forms Deleted

Betamethasone	Ointment 200 micrograms (as valerate) per g, 100 g

Brands Added

Alendronic Acid	Tablet 70 mg (as alendronate sodium) (Alendronate Pfizer)
Amlodipine with valsartan	Tablet 5 mg (as besylate)-80 mg (Valsartan/Amlodipine Sandoz 80/5)
Amlodipine with valsartan and hydrochlorothiazide	Tablet 5 mg (as besylate)-160 mg-12.5 mg (Valsartan/Amlodipine/HCT Sandoz 160/5/12.5)
Amoxycillin with Clavulanic Acid	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 (Pharmacy Choice Anastrozole; STADA Anastrozole)
Atenolol	Tablet 50 mg (Tenolten 50)
Clopidogrel with aspirin	Tablet 75 mg (as hydrogen sulfate)-100 mg (APO-Clopidogrel/Aspirin 75/100; Chem mart Clopidogrel/Aspirin 75/100; Terry White Chemists Clopidogrel/Aspirin 75/100)
Cyproterone	Tablet containing cyproterone acetate 50 mg (Cyproterone-PS) Tablet containing cyproterone acetate 100 mg (Cyproterone-PS 100; Cyproterone Sandoz)
Famciclovir	Tablet 125 mg (Famciclovir-GA) Tablet 250 mg (Famciclovir-GA; Famciclovir generichealth 250) Tablet 500 mg (Famciclovir-GA)
Gemfibrozil	Tablet 600 mg (Gemfibrozil-GA)
Imiquimod	Cream 50 mg per g, 250 mg single use sachets, 12 (APO-Imiquimod)
Lamotrigine	Tablet 25 mg (Reedos 25) Tablet 50 mg (Reedos 50) Tablet 100 mg (Reedos 100) Tablet 200 mg (Reedos 200)
Leflunomide	Tablet 10 mg (Leflunomide-GA) Tablet 20 mg (Leflunomide-GA)
Letrozole	Tablet 2.5 mg (STADA Letrozole)
Loperamide	Capsule containing loperamide hydrochloride 2 mg (Gastrex)
Meloxicam	Tablet 7.5 mg (APO-Meloxicam) Tablet 15 mg (APO-Meloxicam)
Mirtazapine	Tablet 15 mg (APO-Mirtazapine)
Nevirapine	Tablet 200 mg (Nevirapine Alphapharm)
Octreotide	Injection 50 micrograms (as acetate) in 1 mL (Octreotide (SUN)) Injection 100 micrograms (as acetate) in 1 mL (Octreotide (SUN)) Injection 500 micrograms (as acetate) in 1 mL (Octreotide (SUN))
Olanzapine	Wafer 15 mg (Zypine ODT) Wafer 20 mg (Zypine ODT)
Omeprazole	Tablet 20 mg (Omeprazole RBX) Capsule 20 mg (Maxor)
Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated) (APO-Rabeprazole; Chem mart Rabeprazole; Parzole 10; Prabez; Rabeprazole-GA; Rabeprazole generichealth; Rabeprazole Pfizer; Rabeprazole Sandoz; Rabzole; Terry White Chemists Rabeprazole)

	Tablet containing rabeprazole sodium 20 mg (enteric coated) (APO-Rabeprazole; Chem mart Rabeprazole; Parzole 20; Prabez; Rabeprazole-GA; Rabeprazole generichealth; Rabeprazole Pfizer; Rabeprazole Sandoz; Rabzole; Terry White Chemists Rabeprazole)
Ranitidine	Tablet 300 mg (as hydrochloride) (Ranoxyl)
Riluzole	Tablet 50 mg (APO-Riluzole; Riluzole Sandoz)
Risedronic Acid and Calcium	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate) (Actonel Combi)
Sumatriptan	Tablet 50 mg (as succinate) (Sumatriptan RBX)
Terbinafine	Tablet 250 mg (as hydrochloride) (Pharmacy Choice Terbinafine)
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride) (STADA Venlafaxine SR) Capsule (modified release) 150 mg (as hydrochloride) (STADA Venlafaxine SR)

Brands Deleted

Amoxycillin	Capsule 250 mg (as trihydrate) (GenRx Amoxycillin) Capsule 500 mg (as trihydrate) (GenRx Amoxycillin)
Carvedilol	Tablet 3.125 mg (GenRx Carvedilol) Tablet 6.25 mg (GenRx Carvedilol) Tablet 12.5 mg (GenRx Carvedilol)
Cefaclor	Powder for oral suspension 125 mg (as monohydrate) per 5 mL, 100 mL (Cefaclor Sandoz) Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL (Cefaclor Sandoz)
Cefepime	Powder for injection 2 g (as hydrochloride) (Maxipime)
Cephalexin	Granules for oral suspension 125 mg per 5 mL, 100 mL (GenRx Cephalexin) Granules for oral suspension 250 mg per 5 mL, 100 mL (GenRx Cephalexin)
Citalopram	Tablet 20 mg (as hydrobromide) (GenRx Citalopram) Tablet 40 mg (as hydrobromide) (GenRx Citalopram)
Clarithromycin	Tablet 250 mg (GenRx Clarithromycin)
Gemfibrozil	Tablet 600 mg (Lipazil 600 mg)
Lisinopril	Tablet 5 mg (GenRx Lisinopril) Tablet 10 mg (GenRx Lisinopril) Tablet 20 mg (GenRx Lisinopril)
Omeprazole	Tablet 20 mg (GenRx Omeprazole)
Pravastatin	Tablet containing pravastatin sodium 10 mg (GenRx Pravastatin) Tablet containing pravastatin sodium 20 mg (GenRx Pravastatin) Tablet containing pravastatin sodium 40 mg (GenRx Pravastatin)
Simvastatin	Tablet 20 mg (GenRx Simvastatin) Tablet 40 mg (GenRx Simvastatin) Tablet 80 mg (GenRx Simvastatin)

Alteration of Form Description and Brand Name

Listed Drug	**Form**	**Brand**
Glucose Indicator—Blood	*From:* Test strips, 50 (GlucoOz) *To:* Test strips, 50 (GlucoDr)	*From:* GlucoOz *To:* GlucoDr

Alteration of Brand Name

Listed Drug	Form	Brand
Lamivudine	Tablet 150 mg	*From:* Alphapharm Lamivudine *To:* Lamivudine Alphapharm
	Tablet 300 mg	*From:* Alphapharm Lamivudine *To:* Lamivudine Alphapharm

Alteration of Responsible Person

Listed Drug	Form	Brand	Responsible Person
Auranofin	Capsule 3 mg	Ridaura	*From:* Boucher & Muir Pty Ltd (BZ) *To:* Mercury Pharma (Australia) Pty Limited (GH)
Granisetron	Tablet 2 mg (as hydrochloride)	Kytril	*From:* Hospira Pty Limited (HH) *To:* Roche Products Pty Limited (RO)
	Concentrated injection 3 mg (as hydrochloride) in 3 mL	Kytril	*From:* Hospira Pty Limited (HH) *To:* Roche Products Pty Limited (RO)

Alteration of Maximum Quantity

Listed Drug	Form	Max Qty
Apomorphine	Injection containing apomorphine hydrochloride 20 mg in 2 mL	*From:* 5 *To:* 360
	Injection containing apomorphine hydrochloride 50 mg in 5 mL	*From:* 5 *To:* 180
	Solution for subcutaneous infusion containing apomorphine hydrochloride 50 mg in 10 mL pre-filled syringe	*From:* 5 *To:* 180
Clozapine	Tablet 25 mg	*From:* 100 *To:* 200
	Tablet 50 mg	*From:* 100 *To:* 200
	Tablet 100 mg	*From:* 100 *To:* 200
	Tablet 200 mg	*From:* 100 *To:* 200

Alteration of Number of Repeats

Listed Drug	Form	No. of Rpts
Apomorphine	Injection containing apomorphine hydrochloride 20 mg in 2 mL	*From:* 0 *To:* 5
	Injection containing apomorphine hydrochloride 50 mg in 5 mL	*From:* 0 *To:* 5
	Solution for subcutaneous infusion containing apomorphine hydrochloride 50 mg in 10 mL pre-filled syringe	*From:* 0 *To:* 5

Alteration of Authorised Prescriber

Listed Drug	Form	Alteration
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besylate) Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besylate) Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besylate)	Allowance to prescribe extended to authorised Nurse Practitioners

Addition of Responsible Person Code

RI [Dr Reddy's Laboratories (Australia) Pty Ltd]

JS [Janssen-Cilag Pty Ltd]

Deletion of Responsible Person Code

HA [Hamilton Pharmaceutical Pty Ltd]

Alteration of Circumstances

Listed Drug	Alteration
Bortezomib	Circumstances amended to remove the requirement for 24 hour Bence Jones proteinuria quantitation to be provided as evidence of the olgo-secretory nature of multiple myeloma
Denosumab	Authority requirements altered from ‘Authority Required’ to ‘Streamlined Authority Required’ relating to bone metastases from breast cancer and bone metastases from castration-resistant prostate cancer
Ezetemibe with Simvastatin	
Etanercept	Circumstances amended for treatment of severe plaque psoriasis in patients under 18
Pazopanib	
Sunitinib	Circumstances amended relating to renal cell carcinoma
Teriparatide	Circumstances amended to remove reference to disodium etidronate with calcium carbonate

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. 8)

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. 8)* 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 and whether the pharmaceutical benefit is to be available only under special arrangements).

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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