EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2014 (No. 10)

PB 72 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 October 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. 10)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 10)* and may also be cited as PB 72 of 2014.

Section 2 Commencement

This section provides that this Instrument commences on 1 October 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

Listed Drugs Added

Eribulin
Oestradiol with dydrogesterone

Listed Drug Deleted

Polyethylene glycol 400

Forms Added

Glucose Indicator—Blood	Test strips, 50 (EasyMate II) Test strips, 100 (EasyMate II)
Oestradiol and Oestradiol with Dydrogesterone	Pack containing 14 tablets oestradiol 1 mg and 14 tablets oestradiol 1 mg with dydrogesterone 10 mg

Form Deleted

Alendronic Acid	Tablet 40 mg (as alendronate sodium)

Brands Added

Alendronic acid with colecalciferol	Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol (Alendronat plus D3-DRLA; FonatPlus)
Azathioprine	Tablet 50 mg (Imazam)
Capecitabine	Tablet 150 mg (Xelabine)

	Tablet 500 mg (Xelabine)
Doxycycline	Tablet 50 mg (as hydrochloride) (Doxycycline AN) Tablet 100 mg (as hydrochloride) (Doxycycline AN)
Duloxetine	Capsule 30 mg (as hydrochloride) (Pharmacor Duloxetine 30) Capsule 60 mg (as hydrochloride) (Pharmacor Duloxetine 60)
Escitalopram	Tablet 10 mg (as oxalate) (Cilopam-S)
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate) (Esomeprazole GxP) Tablet (enteric coated) 40 mg (as magnesium trihydrate) (Esomeprazole GxP)
Lamotrigine	Tablet 25 mg (Lamotrigine AN) Tablet 50 mg (Lamotrigine AN) Tablet 100 mg (Lamotrigine AN) Tablet 200 mg (Lamotrigine AN)
Macrogol 3350	Sachets containing powder for oral solution 13.125 g with electrolytes, 30 (Macrovic)
Memantine	Tablet containing memantine hydrochloride 10 mg (Memantine generichealth) Tablet containing memantine hydrochloride 20 mg (Memantine generichealth)
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate) (Sozol)
Pramipexole	Tablet containing pramipexole hydrochloride 125 micrograms (Pramipexole AN) Tablet containing pramipexole hydrochloride 250 micrograms (Pramipexole AN) Tablet containing pramipexole hydrochloride 1 mg (Pramipexole AN)
Quetiapine	Tablet 25 mg (as fumarate) (Kaptan) Tablet 100 mg (as fumarate) (Kaptan) Tablet 200 mg (as fumarate) (Kaptan) Tablet 300 mg (as fumarate) (Kaptan)
Riluzole	Tablet 50 mg (Pharmacor Riluzole)
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 (Salbutamol Actavis) Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 (Salbutamol Actavis)
Telmisartan	Tablet 40 mg (Telmisartan RBX) Tablet 80 mg (Telmisartan RBX)
Tramadol	Tablet (sustained release) containing tramadol hydrochloride 100 mg (Tramadol AN SR) Tablet (sustained release) containing tramadol hydrochloride 150 mg (Tramadol AN SR) Tablet (sustained release) containing tramadol hydrochloride 200 mg (Tramadol AN SR)

Brands Deleted

Alprazolam	Tablet 1 mg (Ralozam) Tablet 2 mg (Ralozam)
Amlodipine	Tablet 5 mg (as besylate) (Amlodipine-GA) Tablet 10 mg (as besylate) (Amlodipine-GA)
Carbamazepine	Tablet 100 mg (Carbamazepine Sandoz) *[pack quantity 200 only]* Tablet 200 mg (Carbamazepine Sandoz) *[pack quantity 200 only]*
Ceftriaxone	Powder for injection 2 g (as sodium) (Ceftriaxone ICP)
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)
Mianserin	Tablet containing mianserin hydrochloride 20 mg (Tolvon)
Mirtazapine	Tablet 30 mg (Mirtazapine-DP)

Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated) (Rabzole) Tablet containing rabeprazole sodium 20 mg (enteric coated) (Rabzole)
Salbutamol	Pressurised inhalation 100 micrograms (as sulfate) per dose, 200 doses (CFC-free formulation) (Airomir)
Terbinafine	Tablet 250 mg (as hydrochloride) (Terbinafine-GA)
Topiramate	Tablet 25 mg (Topiramate-GA) Tablet 50 mg (Topiramate-GA) Tablet 100 mg (Topiramate-GA) Tablet 200 mg (Topiramate-GA)

Alteration of Description of Form

Listed Drug	Form
Aclidinium	*From:* Powder for oral inhalation in breath actuated device containing aclidinium bromide 400 micrograms per dose, 60 doses *To:* Powder for oral inhalation in breath actuated device 322 micrograms (as bromide) per dose, 60 doses

Alteration of Responsible Person

Listed Drug	Form	Brand Name	Responsible Person
Acitretin	Capsule 10 mg Capsule 25 mg	Novatin Novatin	*From:* iNova Pharmaceuticals (Australia) Pty Limited (IA) *To:* Apotex Pty Ltd (TX)
Methylprednisolone	Cream containing methylprednisolone aceponate 1 mg per g, 15 g	Advantan	*From:* bioCSL (Australia) Pty Ltd (CS) *To:* Bayer Australia Ltd (BN)
	Ointment containing methylprednisolone aceponate 1 mg per g, 15 g	Advantan	
	Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g	Advantan	
	Lotion containing methylprednisolone aceponate 1 mg per g, 20 g	Advantan	
Moclobemide	Tablet 150 mg	Aurorix	*From:* Meda Valeant Pharma Australia Pty Ltd (VP) *To:* Meda Pharmaceuticals Pty Ltd (HM)
	Tablet 300 mg	Aurorix 300 mg	
Testosterone	Transdermal gel 50 mg in 5 g sachet, 30	Testogel	*From:* Bayer Australia Ltd (BN) *To:* Besins Healthcare Australia Pty Ltd (HB)

Alteration of Authorised Prescriber

Listed Drug	Form	Authorised Prescriber
Strontium	Sachet containing granules for oral suspension containing strontium ranelate 2 g	*From:* MP NP *To:* MP

Alteration of Maximum Quantity, Number of Repeats and Pack Quantity

Listed Drug	Form	
Salbutamol	Capsule containing powder for oral inhalation 200 micrograms (as sulfate) (for use in Ventolin Rotahaler)	***Max Qty*** *From:* 200 *To:* 256 ***No. of Rpts*** *From:* 5 *To:* 4 ***Pack Qty*** *From:* 100 *To:* 128

Addition of Responsible Person Code

Besins Healthcare Australia Pty Ltd [HB]

Eisai Australia Pty Ltd [EI]

Wincot Pty. Limited [WI]

Deletion of Responsible Person Code

AMO Australia Pty Limited [AO]

Janssen-Cilag Pty Ltd [JS]

Meda Valeant Pharma Australia Pty Ltd [VP]

Alteration of Circumstances

Listed Drug	Alteration
Strontium	Circumstances amended to change from "streamlined" to "authority required" The patient must also be at high risk of fracture and must be unable to use other medications for the treatment of osteoporosis due to contraindications or intolerance
Varenicline	Circumstances amended to define length of course of treatment for nicotine dependence and to clarify the criteria for patients undergoing treatment

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. 10)

(PB 72 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. 10)* 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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