EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2013 (No. 13)

PB 74 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 December 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. 13)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 13)* and may also be cited as PB 74 of 2013.

Section 2 Commencement

This section provides that this Instrument commences on 1 December 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

Listed Drugs Added

Alogliptin

Atorvastatin and ezetimibe

Canagliflozin

Dabrafenib

Dapagliflozin

Dimethyl fumarate

Fluticasone with eformoterol

Ivabradine

Olmesartan with amlodipine and hydrochlorothiazide

Rifaximin

Teriflunomide

Forms Added

Amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides	Oral powder 400 g (Alfamino)

Budesonide with Eformoterol	Pressurised inhalation containing budesonide 50 micrograms with eformoterol fumarate dihydrate 3 micrograms per dose, 120 doses, 2 Pressurised inhalation containing budesonide 100 micrograms with eformoterol fumarate dihydrate 3 micrograms per dose, 120 doses, 2 Pressurised inhalation containing budesonide 200 micrograms with eformoterol fumarate dihydrate 6 micrograms per dose, 120 doses, 2
Darunavir	Tablet 800 mg (as ethanolate)
Everolimus	Tablet 2.5 mg Tablet 5 mg Tablet 10 mg
Milk powder—lactose free formula	Oral powder 900 g (Karicare Aptamil Gold De-Lact)
Terbutaline	Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 100 doses
Whey protein formula supplemented with amino acids, long chain polyunsaturated fatty acids, vitamins and minerals, and low in protein, phosphate, potassium and lactose	Oral powder 400 g, 6 (Renastart)

Form Deleted

Ketoconazole	Tablet 200 mg

Brands Added

Candesartan	Tablet containing candesartan cilexetil 4 mg (Auro-Candesartan 4) Tablet containing candesartan cilexetil 8 mg (Auro-Candesartan 8) Tablet containing candesartan cilexetil 16 mg (Auro-Candesartan 16) Tablet containing candesartan cilexetil 32 mg (Auro-Candesartan 32)
Carbimazole	Tablet 5 mg (Carbimazol ARISTO)
Duloxetine	Capsule 30 mg (as hydrochloride) (Deotine 30) Capsule 60 mg (as hydrochloride) (Deotine 60)
Latanoprost	Eye drops 50 micrograms per mL, 2.5 mL (Latanoprost Actavis)
Macrogol 3350	Sachets containing powder for oral solution 13.125 g with electrolytes, 30 (lax-sachets)
Metoprolol	Tablet containing metoprolol tartrate 50 mg (Metatar) Tablet containing metoprolol tartrate 100 mg (Metatar)
Perindopril	Tablet containing perindopril arginine 2.5 mg (PREXUM 2.5) Tablet containing perindopril arginine 5 mg (PREXUM 5) Tablet containing perindopril arginine 10 mg (PREXUM 10)
Perindopril with Indapamide	Tablet containing perindopril arginine 5 mg with indapamide hemihydrate 1.25 mg (Prexum Combi 5/1.25)
Roxithromycin	Tablet 150 mg (Roxithromycin GH) Tablet 300 mg (Roxithromycin GH)
Ziprasidone	Capsule 20 mg (as hydrochloride) (APO-Ziprasidone) Capsule 40 mg (as hydrochloride) (APO-Ziprasidone) Capsule 60 mg (as hydrochloride) (APO-Ziprasidone) Capsule 80 mg (as hydrochloride) (APO-Ziprasidone)

Brands Deleted

Anastrozole	Tablet 1 mg (STADA Anastrozole)

Atorvastatin	Tablet 10 mg (as calcium) (STADA Atorvastatin) Tablet 20 mg (as calcium) (STADA Atorvastatin) Tablet 40 mg (as calcium) (STADA Atorvastatin) Tablet 80 mg (as calcium) (STADA Atorvastatin)
Candesartan	Tablet containing candesartan cilexetil 4 mg (STADA Candesartan) Tablet containing candesartan cilexetil 8 mg (STADA Candesartan) Tablet containing candesartan cilexetil 16 mg (STADA Candesartan) Tablet containing candesartan cilexetil 32 mg (STADA Candesartan)
Candesartan with Hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg (STADA Candesartan HCT 16/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (STADA Candesartan HCT 32/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (STADA Candesartan HCT 32/25)
Clopidogrel	Tablet 75 mg (as besilate) (STADA Clopidogrel)
Donepezil	Tablet containing donepezil hydrochloride 5 mg (STADA Donepezil) Tablet containing donepezil hydrochloride 10 mg (STADA Donepezil)
Irbesartan	Tablet 75 mg (STADA Irbesartan) Tablet 150 mg (STADA Irbesartan) Tablet 300 mg (STADA Irbesartan)
Irbesartan with Hydrochlorothiazide	Tablet 150 mg-12.5 mg (STADA Irbesartan HCT 150/12.5) Tablet 300 mg-12.5 mg (STADA Irbesartan HCT 300/12.5) Tablet 300 mg-25 mg (STADA Irbesartan HCT 300/25)
Letrozole	Tablet 2.5 mg (STADA Letrozole)
Metoprolol	Tablet containing metoprolol tartrate 50 mg (APO-Metoprolol) Tablet containing metoprolol tartrate 100 mg (APO-Metoprolol)
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) Tablet 5 mg (orally disintegrating) (STADA Olanzapine ODT) Tablet 10 mg (orally disintegrating) (STADA Olanzapine ODT)
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) (STADA Pantoprazole)
Quetiapine	Tablet 25 mg (as fumarate) (STADA Quetiapine) Tablet 100 mg (as fumarate) (STADA Quetiapine) Tablet 200 mg (as fumarate) (STADA Quetiapine) Tablet 300 mg (as fumarate) (STADA Quetiapine)
Rabeprazole	Tablet containing rabeprazole sodium 20 mg (enteric coated) (STADA Rabeprazole)
Venlafaxine	Capsule (modified release) 75 mg (as hydrochloride) (STADA Venlafaxine SR) Capsule (modified release) 150 mg (as hydrochloride) (STADA Venlafaxine SR)

Alteration of Form Description

Listed Drug	**Form**
Ifosfamide	*From:* Powder for I.V. injection 1 g in single dose vial *To:* Powder for I.V. injection 1 g *From:* Powder for I.V. injection 2 g in single dose vial *To:* Powder for I.V. injection 2 g

Alteration of Brand Name

Listed Drug	**Form**	**Brand Name**
Ceftriaxone	Powder for injection 1 g (as sodium) Powder for injection 2 g (as sodium)	*From:* DBL Ceftriaxone *To:* Hospira Ceftriaxone

Clarithromycin	Tablet 250 mg	*From:* Clarihexal *To:* Clarithromycin Sandoz
Miconazole	Tincture 20 mg per mL, 30 mL	*From:* Daktarin *To:* Daktarin Tincture

Alteration of Maximum Quantity and Number of Repeats

The listed drug, Ivermectin has been amended to increase the maximum quantity and number of repeats for the strongyloidiasis indication.

Listed Drug	Form	Maximum Quantity	Number of Repeats
Ivermectin	Tablet 3 mg	*From:* 4 *To:* 8	*From:* 0 *To:* 2

Alteration of Number of Repeats

Listed Drug	Form	Number of Repeats
Nicotine	Transdermal patch 17.5 mg	*From:* 0 *To:* 2
	Transdermal patch 35 mg	*From:* 0 *To:* 2

Deletion of Responsible Person Code

STADA Pharmaceuticals Australia Pty Limited [TD]

Alteration of Circumstances

Listed Drug	Alteration
Denosumab	Circumstances amended to remove the criteria which restricts treatment for osteoporosis to female patients only
Ifosfamide	Restrictions have been removed for the use of ifosfamide
Imatinib	Circumstances amended relating to adjuvant treatment following complete resection of primary gastrointestinal stromal tumour (GIST)
Insulin Isophane	A restriction now applies to the injection (bovine) 100 units per mL, 10 mL for the treatment of diabetes mellitus
Insulin Neutral	A restriction now applies to the injection (bovine) 100 units per mL, 10 mL for the treatment of diabetes mellitus
Linagliptin	Circumstances amended to add SGLT2 inhibitors to the classes of anti-diabetic drugs mentioned
Nicotine	Authority Requirements amended to Compliance with Written or Telephone Authority Required procedures - Streamlined Authority
Saxagliptin	Circumstances amended to add SGLT2 inhibitors to the classes of anti-diabetic drugs mentioned
Sitagliptin	Circumstances amended to add SGLT2 inhibitors to the classes of anti-diabetic drugs mentioned
Sitagliptin with metformin	Circumstances amended to add SGLT2 inhibitors to the classes of anti-diabetic drugs mentioned
Sunitinib	Circumstances amended to extend availability for the treatment of metastatic or unresectable, well-differentiated malignant pancreatic neuroendocrine tumour (pNET)
Vildagliptin	Circumstances amended to add SGLT2 inhibitors to the classes of anti-

	diabetic drugs mentioned
Vildagliptin with metformin	Circumstances amended to add SGLT2 inhibitors to the classes of anti-diabetic drugs mentioned

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. 13)

(PB 74 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. 13)* 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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