EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2019 (No. 6)

PB 46 of 2019

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 (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number 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). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

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 Pharmaceutical Benefits Advisory Committee (PBAC) has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

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.

Subsection 85(6A) provides that the Minister may also determine for the purposes of paragraph 103(2A)(b) that a brand of a pharmaceutical item determined under subsection 85(6) is to be treated as equivalent to one or more other brands of pharmaceutical items.

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.

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

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 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, and the circumstances for prescribing various pharmaceutical benefits (including authority requirements) and equivalent brands. These changes are summarised, by subject matter, in the Attachment.

Consultation

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The 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 to Australians as pharmaceutical benefits. The 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 the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. 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.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

General

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

This Instrument commences on 1 July 2019.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

ATTACHMENT

PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2019 (No. 6)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 6)* and may also be cited as PB 46 of 2019.

Section 2 Commencement

This section provides that this Instrument commences on 1 July 2019.

Section 3 Amendment of *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 drugs, forms, brands, responsible person codes, the circumstances for prescribing various pharmaceutical benefits (including authority requirements) and equivalent brands. These changes are summarised below.

SUMMARY OF CHANGES

Listed Drugs Deleted

Abciximab

Cystine with carbohydrate

Pyrimethamine

Rosiglitazone with metformin

Forms Added

Isotretinoin	Capsule 5 mg
Phenelzine	Tablet 15 mg (as sulfate) (USP)

Forms Deleted

Amino acid formula with vitamins and minerals without phenylalanine	Oral powder 500 g (XP Maxamaid)
Glatiramer	Injection containing glatiramer acetate 20 mg in 1 mL single dose pre-filled syringe
Ritonavir	Oral solution 600 mg per 7.5 mL (80 mg per mL), 90 mL

Brands Added

Celecoxib	Capsule 100 mg (*Celecoxib BTC; GenRx Celecoxib*) Capsule 200 mg (*Celecoxib BTC; GenRx Celecoxib*)
Fenofibrate	Tablet 48 mg (*Fenofibrate Mylan*) Tablet 145 mg (*Fenofibrate Mylan*)

Isosorbide mononitrate	Tablet 60 mg (sustained release) (*APO-Isosorbide Mononitrate*)
Montelukast	Tablet, chewable, 4 mg (as sodium) (*Montelukast APOTEX*) Tablet, chewable, 5 mg (as sodium) (*Montelukast APOTEX*)
Olmesartan with amlodipine	Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) (*Olmesartan/Amlodipine 20/5 APOTEX*) Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) (*Olmesartan/Amlodipine 40/5 APOTEX*) Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) (*Olmesartan/Amlodipine 40/10 APOTEX*)
Paracetamol	Tablet 500 mg (*Paracetamol Generic Health*)
Raloxifene	Tablet containing raloxifene hydrochloride 60 mg (*Raloxifene GH*)
Temozolomide	Capsule 5 mg (*Temozolomide Juno*) Capsule 20 mg (*Temozolomide Juno*) Capsule 100 mg (*Temozolomide Juno*) Capsule 140 mg (*Temozolomide Juno*) Capsule 180 mg (*Temozolomide Juno*) Capsule 250 mg (*Temozolomide Juno*)
Tirofiban	Solution concentrate for I.V. infusion 12.5 mg (as hydrochloride) in 50 mL (*Tirofiban Juno*)
Ziprasidone	Capsule 20 mg (as hydrochloride) (*Ziprasidone GH*) Capsule 40 mg (as hydrochloride) (*Ziprasidone GH*) Capsule 60 mg (as hydrochloride) (*Ziprasidone GH*) Capsule 80 mg (as hydrochloride) (*Ziprasidone GH*)
Zoledronic acid	Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL (*DEZTRON*)

Brands Deleted

Amoxicillin with clavulanic acid	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (*Chem mart Amoxycillin and Clavulanic Acid*; *Terry White Chemists Amoxycillin and Clavulanic Acid*)
Atorvastatin	Tablet 10 mg (as calcium) (*Chem mart Atorvastatin*) Tablet 20 mg (as calcium) (*Chem mart Atorvastatin*) Tablet 40 mg (as calcium) (*Chem mart Atorvastatin*) Tablet 80 mg (as calcium) (*Chem mart Atorvastatin*)
Bosentan	Tablet 62.5 mg (as monohydrate) (*Bosentan APOTEX*) Tablet 125 mg (as monohydrate) (*Bosentan APOTEX*)
Candesartan	Tablet containing candesartan cilexetil 4 mg (*Chem mart Candesartan; Terry White Chemists Candesartan*) Tablet containing candesartan cilexetil 8 mg (*Chem mart Candesartan; Terry White Chemists Candesartan*) Tablet containing candesartan cilexetil 16 mg (*Chem mart Candesartan; Terry White Chemists Candesartan*) Tablet containing candesartan cilexetil 32 mg (*Chem mart Candesartan; Terry White Chemists Candesartan*)
Candesartan with hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg (*Chem mart Candesartan HCTZ 16/12.5; Terry White Chemists Candesartan HCTZ 16/12.5*)

	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (*Chem mart Candesartan HCTZ 32/12.5; Terry White Chemists Candesartan HCTZ 32/12.5*)
	Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (*Chem mart Candesartan HCTZ 32/25; Terry White Chemists Candesartan HCTZ 32/25*)
Clarithromycin	Tablet 250 mg (*Chem mart Clarithromycin; Terry White Chemists Clarithromycin*)
Clopidogrel with aspirin	Tablet 75 mg (as hydrogen sulfate)-100 mg (*Chem mart Clopidogrel/Aspirin 75/100; Terry White Chemists Clopidogrel/Aspirin 75/100*)
Fluorometholone	Eye drops 1 mg per mL, 5 mL (*Flucon*)
Indapamide	Tablet containing indapamide hemihydrate 1.5 mg (sustained release) (*Chem mart Indapamide SR; Terry White Chemists Indapamide SR*)
Irbesartan	Tablet 75 mg (*Abisart*)
	Tablet 150 mg (*Abisart*)
	Tablet 300 mg (*Abisart*)
Irbesartan with hydrochlorothiazide	Tablet 150 mg-12.5 mg (*Abisart HCT 150/12.5*)
	Tablet 300 mg-12.5 mg (*Abisart HCT 300/12.5*)
	Tablet 300 mg-25 mg (*Abisart HCT 300/25*)
Lercanidipine	Tablet containing lercanidipine hydrochloride 10 mg (*Chem mart Lercanidipine; Terry White Chemists Lercanidipine*)
	Tablet containing lercanidipine hydrochloride 20 mg (*Chem mart Lercanidipine; Terry White Chemists Lercanidipine*)
Letrozole	Tablet 2.5 mg (*Chem mart Letrozole; Terry White Chemists Letrozole*)
Metformin	Tablet containing metformin hydrochloride 500 mg (*Formet Aspen 500*)
	Tablet containing metformin hydrochloride 850 mg (*Formet Aspen 850*)
Metoprolol succinate	Tablet 23.75 mg (controlled release) (*Toprol-XL 23.75*)
Moclobemide	Tablet 150 mg (*GenRx Moclobemide*)
Olanzapine	Tablet 2.5 mg (*Chem mart Olanzapine; Terry White Chemists Olanzapine*)
	Tablet 5 mg (*Chem mart Olanzapine; Terry White Chemists Olanzapine*)
	Tablet 7.5 mg (*Chem mart Olanzapine; Terry White Chemists Olanzapine*)
	Tablet 10 mg (*Chem mart Olanzapine; Terry White Chemists Olanzapine*)
Omeprazole	Tablet 20 mg (*Chem mart Omeprazole; Terry White Chemists Omeprazole*)
Paracetamol	Tablet 500 mg (*Generic Health Pty Ltd*)
Pioglitazone	Tablet 15 mg (as hydrochloride) (*Chem mart Pioglitazone; Terry White Chemists Pioglitazone*)
	Tablet 30 mg (as hydrochloride) (*Chem mart Pioglitazone; Terry White Chemists Pioglitazone*)
	Tablet 45 mg (as hydrochloride) (*Chem mart Pioglitazone; Terry White Chemists Pioglitazone*)
Ramipril	Capsule 2.5 mg (*Chem mart Ramipril; Terry White Chemists Ramipril*)
	Capsule 5 mg (*Chem mart Ramipril; Terry White Chemists Ramipril*)
	Capsule 10 mg (*Chem mart Ramipril; Terry White Chemists Ramipril*)
	Tablet 2.5 mg (*Chem mart Ramipril; Terry White Chemists Ramipril*)
	Tablet 5 mg (*Chem mart Ramipril; Terry White Chemists Ramipril*)

Sumatriptan	Tablet 50 mg (as succinate) (*Chem mart Sumatriptan; Terry White Chemists Sumatriptan*)
Valaciclovir	Tablet 500 mg (as hydrochloride) (*Chem mart Valaciclovir; Terry White Chemists Valaciclovir*)

Addition of Responsible Person

Oraderm Pharmaceuticals Pty Ltd (*OU*)

Alteration of Circumstances

Pemetrexed

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 2019 (No. 6)

(PB 46 of 2019)

This 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 Instrument

The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2019 (No. 6)* amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (the Principal Instrument) 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, schedule equivalence, maximum quantities, number 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, schedule equivalence, 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 Instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights 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. The pharmaceutical industry now has a nominee on the PBAC membership.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

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