EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2014 (No. 2)

PB 9 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 March 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. 2)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 2)* and may also be cited as PB 9 of 2014.

Section 2 Commencement

This section provides that this Instrument commences on 1 March 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

Arachidonic acid and docosahexaenoic acid with carbohydrate

Carbohydrate, fat, vitamins, minerals and trace elements and supplemented with arachidonic acid and docosahexaenoic acid

Docosahexaenoic acid with carbohydrate

Linagliptin with metformin

Saxagliptin with metformin

Triglycerides, long chain

Forms Added

Bimatoprost	Eye drops 300 micrograms per mL, single dose units 0.4 mL, 30
Triglycerides, medium chain	Oral liquid 250 mL, 18 (betaquik)

Forms Deleted

Amino acid formula with vitamins and minerals without phenylalanine	Oral powder 400 g (Phenex-2)
Somatropin	Injection 5 mg (15 i.u.) in 1 mL cartridge (with preservative)
Terbutaline	Powder for oral inhalation in breath actuated device containing terbutaline sulfate 500 micrograms per dose, 200 doses

Brands Added

Amoxycillin with Clavulanic Acid	Tablet containing 875 mg amoxycillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) (Clavam 875 mg/125 mg)
Anastrozole	Tablet 1 mg (Azastrole)
Bicalutamide	Tablet 50 mg (Bicalox)
Imiquimod	Cream 50 mg per g, 250 mg single use sachets, 12 (Aldiq)
Lisinopril	Tablet 5 mg (Auro-Lisinopril 5) Tablet 10 mg (Auro-Lisinopril 10) Tablet 20 mg (Auro-Lisinopril 20)
Nevirapine	Tablet 200 mg (Nevipin)
Pantoprazole	Tablet (enteric coated) 40 mg (as sodium sesquihydrate) (Topra 40)
Risperidone	Tablet 0.5 mg (Rispernia) Tablet 1 mg (Rispernia) Tablet 2 mg (Rispernia) Tablet 3 mg (Rispernia) Tablet 4 mg (Rispernia)
Temozolomide	Capsule 5 mg (Temozolomide Alphapharm) Capsule 20 mg (Temozolomide Alphapharm) Capsule 100 mg (Temozolomide Alphapharm) Capsule 140 mg (Temozolomide Alphapharm) Capsule 250 mg (Temozolomide Alphapharm)

Brands Deleted

Amlodipine	Tablet 5 mg (as besylate) (Amlodipine Pfizer) Tablet 10 mg (as besylate) (Amlodipine Pfizer)
Carboplatin	Solution for I.V. injection 150 mg in 15 mL (Pfizer Australia Pty Ltd)
Cisplatin	I.V. injection 50 mg in 50 mL (Pfizer Australia Pty Ltd) I.V. injection 100 mg in 100 mL (Pfizer Australia Pty Ltd)
Dicloxacillin	Capsule 500 mg (as sodium) (Diclocil)
Epirubicin	Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL (Epirubicin Kabi)
Fludarabine	Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL (AS-Fludarabine)
Gabapentin	Capsule 100 mg (Gabapentin Pfizer) Capsule 300 mg (Gabapentin Pfizer) Capsule 400 mg (Gabapentin Pfizer) Tablet 800 mg (Gabapentin Pfizer)
Gemcitabine	Powder for I.V. infusion 200 mg (as hydrochloride) (Gemcitabine Kabi) Powder for I.V. infusion 2 g (as hydrochloride) (Gemcitabine Kabi) Solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL (Gemcitabine-AS) Solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL (Gemcitabine-AS)
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL (Irinotecan Kabi)
Lactulose	Solution BP 3.34 g per 5 mL, 500 mL (Lactocur)
Mitozantrone	Injection 20 mg (as hydrochloride) in 10 mL (Pfizer Australia Pty Ltd)
Olanzapine	Tablet 2.5 mg (Zylap 2.5) Tablet 5 mg (Zylap 5) Tablet 7.5 mg (Zylap 7.5) Tablet 10 mg (Zylap 10) Tablet 5 mg (orally disintegrating) (Zylap ODT 5) Tablet 10 mg (orally disintegrating) (Zylap ODT 10)

Oxaliplatin	Solution concentrate for I.V. infusion 50 mg in 10 mL (Oxaliplatin Kabi)
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL (Taxol) Solution concentrate for I.V. infusion 100 mg in 16.7 mL (Paclitaxel Kabi; Taxol) Solution concentrate for I.V. infusion 300 mg in 50 mL (Taxol)
Quinapril	Tablet 5 mg (as hydrochloride) (Quinapril Pfizer) Tablet 10 mg (as hydrochloride) (Quinapril Pfizer) Tablet 20 mg (as hydrochloride) (Quinapril Pfizer)
Sertraline	Tablet 50 mg (as hydrochloride) (Sertraline Pfizer) Tablet 100 mg (as hydrochloride) (Sertraline Pfizer)

Alteration of Brand Name

Listed Drug	Form	Brand Name
Sertraline	Tablet 50 mg (as hydrochloride) Tablet 100 mg (as hydrochloride)	*From:* Sertraline-GA *To:* Sertraline Actavis*

*Along with this alteration of brand name the circumstances which can be prescribed for this brand are extended to include all circumstances for these forms of sertraline.

Alteration of Responsible Person

Listed Drug	Form	Brand Name	Responsible Person
Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 80 mg (anhydrous) in 2 mL with solvent	AS-Docetaxel	*From:* Agila Australasia Pty Ltd (YA) *To:* Alphapharm Pty Ltd (AF)
Felodipine	Tablet 2.5 mg (extended release) Tablet 5 mg (extended release) Tablet 10 mg (extended release)	Plendil ER Plendil ER Plendil ER	*From:* AstraZeneca Pty Ltd (AP) *To:* Apotex Pty Ltd (GX)
Topotecan	Powder for I.V. infusion 4 mg (as hydrochloride)	Topotecan Agila	*From:* Agila Australasia Pty Ltd (YA) *To:* Alphapharm Pty Ltd (AF)

Addition of Responsible Person Code

Norac Pharma Australia Pty Ltd [NJ]

Deletion of Responsible Person Code

Agila Australasia Pty Ltd [YA]

Alteration of Circumstances

Listed Drug	Alteration
Pazopanib	Circumstances amended to extend availability of pazopanib for the treatment of soft tissue sarcoma

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. 2)

(PB 9 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. 2)* 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.

Felicity McNeill
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health