EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH ACT (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2012 (No. 9)

PB 108 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 January 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 2012 (No. 9)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2012 (No. 9)* and may also be cited as PB 108 of 2012.

Section 2 Commencement

This section provides that this Instrument commences on 1 January 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

Forms Deleted

Betamethasone	Ointment 500 micrograms (as valerate) per g, 15 g
Tramadol	Tablet (extended release) containing tramadol hydrochloride 100 mg Tablet (extended release) containing tramadol hydrochloride 200 mg Tablet (extended release) containing tramadol hydrochloride 300 mg

Brands Added

Famciclovir	Tablet 500 mg (Famciclovir generichealth 500)
Felodipine	Tablet 2.5 mg (extended release) (Fendex ER) Tablet 5 mg (extended release) (Fendex ER) Tablet 10 mg (extended release) (Fendex ER)
Fentanyl	Transdermal patch 2.063 mg (Dutran 12) Transdermal patch 4.125 mg (Dutran 25) Transdermal patch 8.25 mg (Dutran 50) Transdermal patch 12.375 mg (Dutran 75) Transdermal patch 16.5 mg (Dutran 100)
Fluoxetine	Capsule 20 mg (as hydrochloride) (Auscap Aspen)
Lamotrigine	Tablet 25 mg (Lamotrigine Aspen 25) Tablet 100 mg (Lamotrigine Aspen 100)

Rabeprazole	Tablet containing rabeprazole sodium 10 mg (enteric coated) (Razit 10) Tablet containing rabeprazole sodium 20 mg (enteric coated) (Razit 20; STADA Rabeprazole)
Risperidone	Tablet 0.5 mg (Rispericor 0.5) Tablet 1 mg (Rispericor 1) Tablet 2 mg (Rispericor 2) Tablet 3 mg (Rispericor 3) Tablet 4 mg (Rispericor 4)

Brands Deleted

Fluoxetine	Capsule 20 mg (as hydrochloride) (Auscap)
Macrogol 3350	Powder for oral solution 510 g (your pharmacy Clear Laxative)
Mycophenolic acid	Capsule containing mycophenolate mofetil 250 mg (Cellplant) Tablet containing mycophenolate mofetil 500 mg (Cellplant)
Risperidone	Tablet 0.5 mg (Resdone 0.5) Tablet 1 mg (Resdone 1) Tablet 2 mg (Resdone 2) Tablet 3 mg (Resdone 3) Tablet 4 mg (Resdone 4)
Terbinafine	Tablet 250 mg (as hydrochloride) (Terbix 250)
Tramadol	Capsule containing tramadol hydrochloride 50 mg (GenRx Tramadol)

Alteration of Responsible Person

Listed Drug	Form	Brand	Responsible Person
Bicalutamide	Tablet 50 mg	Cosudex	*From:* Sandoz Pty Ltd (SZ) *To:* AstraZeneca Pty Ltd (AP)
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Panto	*From:* Nycomed Services Pty Limited (NZ)
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Panto	*To:* Takeda Pharmaceuticals Australia Pty Ltd (TK)
Pantoprazole	Tablet (enteric coated) 20 mg (as sodium sesquihydrate)	Pantoloc	*From:* Nycomed Healthcare Pty Limited (NH)
	Tablet (enteric coated) 40 mg (as sodium sesquihydrate)	Pantoloc	*To:* Takeda Pharmaceuticals Australia Pty Ltd (TE)

Addition of Responsible Person Code

TE [Takeda Pharmaceuticals Australia Pty Ltd]

TK [Takeda Pharmaceuticals Australia Pty Ltd]

Name Change of Responsible Person

NQ [*From:* Nycomed Pty Ltd *To:* Takeda Pharmaceuticals Australia Pty Ltd]

Deletion of Responsible Person Code

NH [Nycomed Healthcare Pty Limited]

NZ [Nycomed Services Pty Limited]

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. 9)

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. 9)* 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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