EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2013 (No. 10)

PB 53 of 2013

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88, 99AEH, 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

PB 71 of 2012 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).

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)).

Paragraph 99AEH(2)(a) of the Act allows the Minister, by legislative instrument, to revoke a subsection 85(6) determination that a guaranteed brand of a guaranteed item is a listed brand where a responsible person for a guaranteed brand is unable to supply the guaranteed brand on one or more occasions.

The Minister's delegate, having had regard to matters set out in subsection 99AEH(3) of the Act, is delisting the Rabeprazole Actavis 20 brand of the listed drug rabeprazole in the form tablet containing rabeprazole sodium 20 mg (enteric coated). This brand was first listed on 1 July 2013.

The delisting will not impact the availability of this strength of rabeprazole, tablet containing rabeprazole sodium 20 mg (enteric coated) to patients, as other substitutable brands are available on the PBS. The drug company are able to apply to relist this brand on the PBS with appropriate assurances of continuity of supply.

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 September 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. 10)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2013 (No. 10)* and may also be cited as PB 53 of 2013.

Section 2 Commencement

This section provides that this Instrument commences on 1 September 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

Addition of Listed Drugs

Tafluprost

Forms Added

Apixaban	Tablet 5 mg
Dabigatran etexilate	Capsule 150 mg (as mesilate)
Filgrastim	Injection 300 micrograms in 0.5 mL single use pre-filled syringe (Zarzio) Injection 480 micrograms in 0.5 mL single use pre-filled syringe (Zarzio)
Flutamide	Tablet 250 mg, 30
Raltegravir	Tablet 25 mg (as potassium) Tablet 100 mg (as potassium)

Forms Deleted

Buprenorphine with naloxone	Tablet (sublingual) 2 mg (as hydrochloride)-0.5 mg (as hydrochloride) Tablet (sublingual) 8 mg (as hydrochloride)-2 mg (as hydrochloride)
Salbutamol	Nebuliser solution 5 mg (as sulfate) per mL, 30 mL

Brands Added

Cefepime	Powder for injection 1 g (as hydrochloride) (Cefepime-AFT) Powder for injection 2 g (as hydrochloride) (Cefepime-AFT)

Candesartan with Hydrochlorothiazide	Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg (Candesartan/HCT Sandoz; Pharmacor Candesartan HCT 16/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (Candesartan/HCT Sandoz; Pharmacor Candesartan HCT 32/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (Candesartan/HCT Sandoz; Pharmacor Candesartan HCT 32/25)
Famciclovir	Tablet 250 mg (Auro-Famciclovir 250)
Gemcitabine	Powder for I.V. infusion 2 g (as hydrochloride) (Gemcitabine Actavis 2000)
Granisetron	Concentrated injection 3 mg (as hydrochloride) in 3 mL (Granisetron-AFT)
Hydroxychloroquine	Tablet containing hydroxychloroquine sulfate 200 mg (Hydroxychloroquine Actavis)
Montelukast	Tablet, chewable, 4 mg (as sodium) (Pharmacor Montelukast 4) Tablet, chewable, 5 mg (as sodium) (Pharmacor Montelukast 5)

Brands Deleted

Cyproterone	Tablet containing cyproterone acetate 50 mg (Cyprohexal) Tablet containing cyproterone acetate 100 mg (Cyprohexal)
Gemcitabine	Powder for I.V. infusion 200 mg (as hydrochloride) (Gemzar) Powder for I.V. infusion 1 g (as hydrochloride) (Gemzar)
Metformin	Tablet containing metformin hydrochloride 500 mg (Formet 500) Tablet containing metformin hydrochloride 850 mg (Formet 850)
Misoprostol	Tablet 200 micrograms (Cytotec) *[see also Alteration of Circumstances]*
Norfloxacin	Tablet 400 mg (Noroxin)
Ondansetron	I.V. injection 4 mg (as hydrochloride dihydrate) in 2 mL (Zofran) I.V. injection 8 mg (as hydrochloride dihydrate) in 4 mL (Zofran)
Paclitaxel	Solution concentrate for I.V. infusion 30 mg in 5 mL (Paclitaxel Pfizer) Solution concentrate for I.V. infusion 100 mg in 16.7 mL (Paclitaxel Pfizer)
Quinapril	Tablet 5 mg (as hydrochloride) (Aquin 5) Tablet 10 mg (as hydrochloride) (Aquin 10) Tablet 20 mg (as hydrochloride) (Aquin 20)
Rabeprazole	Tablet containing rabeprazole sodium 20 mg (enteric coated) (Rapebrazole Actavis 20)
Risedronic Acid and Calcium	Pack containing 4 tablets risedronate sodium 35 mg and 24 tablets calcium 500 mg (as carbonate) (Actonel Combi)
Sumatriptan	Tablet 50 mg (as succinate) (Sumagran 50)

Alteration of Brand Name

Listed Drug	Form	Brand Name
Duloxetine	Capsule 30 mg (as hydrochloride) Capsule 60 mg (as hydrochloride)	*From:* Duloxetine DR GH *To:* Duloxetine GH

Alteration of Circumstances

Listed Drug	Alteration
Apixaban	Circumstances amended to extend availability for the prevention of stroke or systemic embolism in a patient with non-valvular atrial fibrillation
Dabigatran etexilate	Circumstances amended to extend availability for the prevention of stroke or systemic embolism in a patient with non-valvular atrial fibrillation
Misoprostol	Circumstances amended to remove indications for the reduction of gastrointestinal complications in patients who have a history of peptic ulcers, and for the treatment of duodenal and gastric ulcers following the deletion of the brand Cytotec

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. 10)

(PB 53 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. 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 and whether the pharmaceutical benefit is to be available only under special arrangements).

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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