EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2021 (No. 7)

PB 74 of 2021

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).

This legislative instrument also amends PB 71 of 2012 to ensure that medical practitioners are authorised to prescribe extemporaneously-prepared pharmaceutical benefits. This amendment rectifies the inadvertent removal of authorised prescribers for extemporaneously-prepared pharmaceutical benefits by the *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020* (Supply Only Instrument).

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

Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including medical practitioners (subsection 88(1)), 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.

Paragraph 88(1EB) provides that the Minister can list pharmaceutical benefits without determining any authorised prescribers for the benefit allowing the benefit to be supplied only.

This legislative instrument is made pursuant to section 88 and subsection 100(2) of the *National Health Act 1953* (the Act).

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 - Authorised prescriber for extemporaneously-prepared pharmaceutical benefits

Schedule 1 makes amendments to PB 71 of 2012 to authorise medical practitioners to write prescriptions for the supply of extemporaneously-prepared pharmaceutical benefits. The amendments in Schedule 1 commence retrospectively on 1 November 2020.

This date reflects the commencement date of amendments to PB 71 of 2012 made by the Supply Only Instrument, which inadvertently removed the authorised prescribers for extemporaneously-prepared pharmaceutical benefits. Consistent with the provisions of PB 71 of 2012 before the Supply Only Instrument came into effect, it was always intended that medical pracitioners would be authorised to prescribe extemporaneously-prepared pharmaceutical benefits.

Section 12 of the *Legislation Act 2003* permits provisions of a legislative instrument to commence retrospectively, provided that they do not disadvantage or impose liabilities on a person other than the Commonwealth. The retrospective amendments do not operate to the disadvantage of any person other than the Commonwealth. Rather, the amendments support the intended operation of the Act by ensuring that claims for supplies of extemporaneously-prepared pharmaceutical benefits prescribed by medical practitioners on and after 1 November 2020 are payable.

The amendments made in Schedule 1 of this Instrument are made in accordance with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC) as required by paragraph 88(1EA). Paragraph 88(1EA) provides that the Minister must consider any advice given by the Pharmaceutical Benefits Advisory Committee when determining authorised prescribers for a pharmaceutical benefit.

Schedule 2 - Other amendments

Schedule 2 to this Instrument provides for the addition of the listed drugs alirocumab, fremanezumab, and risdiplam, and the addition of forms of the listed drugs adrenaline (epinephrine), and paraffin to the Schedule of Pharmaceutical Benefits. It also provides for the deletion of the listed drugs parffin soft yellow, and red syrup from the list of extemporaneously-prepared pharmaceutical benefits. Additionally, it provides for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs atezolizumab, blinatumomab, botulinum toxin type A purified neurotoxin complex, cetuximab, clostridium botulinum type A toxin - haemagglutinin complex, evolocumab, galcanezumab, panitumumab, and pembrolizumab.

Schedule 2 to this Instrument also provides for the following changes:

- the addition of 30 brands of existing pharmaceutical items;
- the addition of 2 responsible person codes for existing brands of pharmaceutical items;
- the alteration of responsible person codes for 4 existing brands of pharmaceutical items; and
- the addition of 7 brands of existing pharmaceutical items to supply only.

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.

Sections 1 to 4 and Schedule 2 to this Instrument commence on 1 August 2021. Schedule 1 to this Instrument commences retrospectively on 1 November 2020.

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 2021 (No. 7)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021 (No. 7)* and may also be cited as PB 74 of 2021.

Section 2 Commencement

Subsection 2(1) provides for commencement dates of each of the provisions specified in Column 1 of the table, in accordance with Column 2 of the table. In accordance with Column 2 of the table, sections 1-4 and Schedule 2 to the Instrument commence on 1 August 2021. The amendments in Schedule 1 to the Instrument commence retrospectively on 1 November 2020.

Section 3 Authority

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

Section 4 Schedules

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms. There are two Schedules to this Instrument:

- Schedule 1 sets out amendments to PB 71 of 2012 related to authorised prescribers
- Schedule 2 sets out other amendments to PB 71 of 2012.

Schedule 1 Authorised prescriber amendments

Item 1

Item 1 of Schedule 1 amends the definition of authorised prescriber in section 4 of PB 71 of 2012. The amended definition provides that authorised prescribers are the PBS prescribers (as defined by the Act) who are authorised to write prescriptions for the supply of pharmaceutical benefits under the existing section 9 (relating to ready-prepared pharmaceutical benefits) and the new section 9A (relating to extemporaneously-prepared pharmaceutical benefits).

The definition is being amended so that it encompasses prescribers who are authorised to prescribe pharmaceutical benefits under the new section 9A.

Item 2

Item 2 of Schedule 1 inserts a new section 9A into PB 71 of 2012. The new section 9A provides that medical practitioners are authorised to prescribe extemporaneously-prepared pharmaceutical benefits, in line with PBAC's recommendation. This amendment is intended to re-instate the arrangements under PB 71 of 2012 before the amendments made by the Supply Only Instrument on 1 November 2020 inadvertently removed authorised prescribers for extemporaneously-prepared pharmaceutical benefits.

Schedule 2 Other amendments

The amendments in Schedule 2 involve the addition of listed drugs, the addition of forms of listed drugs, the addition of brands, the addition and alteration of responsible person codes for brands of pharmaceutical benefits, the addition of 7 brands of pharmaceutical items to supply only status, the deletion of listed drugs from the list of extemporaneously-prepared pharmaceutical benefits, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme. These changes are summarised below.

SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME MADE BY SCHEDULE 2 OF THIS INSTRUMENT

Listed Drugs Added

Listed Drug
Alirocumab
Fremanezumab
Risdiplam

Listed Drugs Deleted - Extemporaneously-prepared pharmaceutical benefits

Listed Drug
Paraffin Soft Yellow
Red Syrup

Forms Added

Listed Drug	*Form*
Adrenaline (epinephrine)	Solution for injection 1 mg (as tartrate) in 1 mL (1 in 1,000)
Paraffin	Eye drops containing liquid paraffin, glycerol, tyloxapol, poloxamer-188, trometamol hydrochloride, trometamol, cetalkonium chloride, 10 mL (preservative free)

Brands Added

Listed Drug	*Form and Brand*
Aciclovir	Eye ointment 30 mg per g, 4.5 g *(XOROX)*
Atenolol	Tablet 50 mg *(APX-Atenolol)*
Azathioprine	Tablet 25 mg *(NOUMED AZATHIOPRINE)*
	Tablet 50 mg *(NOUMED AZATHIOPRINE)*
Bisoprolol	Tablet containing bisoprolol fumarate 2.5 mg *(Bisoprolol Dr.Reddy's)*
	Tablet containing bisoprolol fumarate 5 mg *(Bisoprolol Dr.Reddy's)*
	Tablet containing bisoprolol fumarate 10 mg *(Bisoprolol Dr.Reddy's)*
Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses *(BiResp Spiromax)*
	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2 *(BiResp Spiromax)*
Clarithromycin	Tablet 250 mg *(NOUMED CLARITHROMYCIN)*
Colchicine	Tablet 500 micrograms *(Colcine)*
Deferasirox	Tablet 90 mg *(CIPLA DEFERASIROX; Eferas; Pharmacor Deferasirox FC)*

	Tablet 180 mg *(CIPLA DEFERASIROX; Eferas; Pharmacor Deferasirox FC)*
	Tablet 360 mg *(CIPLA DEFERASIROX; Eferas; Pharmacor Deferasirox FC)*
Ondansetron	Tablet (orally disintegrating) 4 mg *(APX-Ondansetron ODT)*
	Tablet 4 mg (as hydrochloride dihydrate) *(APX-Ondansetron)*
	Tablet (orally disintegrating) 8 mg *(APX-Ondansetron ODT)*
	Tablet 8 mg (as hydrochloride dihydrate) *(APX-Ondansetron)*
Paracetamol	Tablet 500 mg *(Paracetamol Sandoz Pharma; Wagner Health Paracetamol)*
Paroxetine	Tablet 20 mg (as hydrochloride) *(APX-Paroxetine)*
Roxithromycin	Tablet 150 mg *(APX-Roxithromycin)*
	Tablet 300 mg *(APX-Roxithromycin)*
Valganciclovir	Tablet 450 mg (as hydrochloride) *(VALGANCICLOVIR HETERO)*

Addition of Responsible Person Code

Gem Pharma Pty Ltd *(GG)*

Sandoz Pty Ltd *(QS)*

Alteration of Responsible Person Code

Listed Drug	***Form***	***Brand Name***	***Responsible Person***
Clonazepam	Injection 1 mg in 2 mL (set containing solution 1 mg in 1 mL and 1 mL diluent)	*Rivotril*	***From:*** RO ***To:*** PB
	Oral liquid 2.5 mg per mL, 10 mL	*Rivotril*	***From:*** RO ***To:*** PB
	Tablet 500 micrograms	*Rivotril*	***From:*** RO ***To:*** PB
Diazepam	Tablet 5 mg	*Valium*	***From:*** RO ***To:*** IX

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug	***Listed Drug***
Atezolizumab	Evolocumab
Blinatumomab	Galcanezumab
Botulinum toxin type A purified neurotoxin complex	Panitumumab
Cetuximab	Pembrolizumab
Clostridium botulinum type A toxin - haemagglutinin complex	

Supply Only Status

Note: *From 1 November 2020 Supply Only benefits are available on the Schedule for dispensing but not for prescribing, usually for a period of up to 12 months from when it is deleted.*

Listed Drug	***Form and Brand***
Acarbose	Tablet 100 mg *(Glucobay 100)*
Exenatide	Injection (modified release) 2 mg single dose pre-filled pen *(Bydureon)*
Ramipril	Capsule 10 mg *(Ramace 10 mg)*
	Tablet 1.25 mg *(Ramace 1.25 mg)*
	Tablet 2.5 mg *(Ramace 2.5 mg)*
	Tablet 5 mg *(Ramace 5 mg)*
Valganciclovir	Tablet 450 mg (as hydrochloride) *(Valcyte)*

Documents Incorporated by Reference

Listed Drug	***Document incorporated***	***Document access***
Alirocumab Evolocumab	**Dutch Lipid Clinic Network Score (DLCNS).** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the Legislation Act 2003. The DLCNS is a validated set of criteria used to categorise the likelihood of a patient having Familial Hypercholesterolaemia, by evaluating family history of premature cardiovascular disease (CVD) in first degree relatives, the patient's own CVD history, their untreated lipid levels and physical signs such as the presence of tendon xanthomata or arcus cornealis prior to the age of 45.	The DLCNS is available for download for free from the Royal Australian College of General Practitioners website https://www.racgp.org.au/FSDEDEV/media/documents/Clinical%20Resources/Guidelines/Red%20Book/Appendix-2B.pdf
Alirocumab Evolocumab	**Therapeutic Goods Administration (TGA)-approved Product Information.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*. This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.	TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0
Alirocumab Evolocumab	**Thrombolysis in Myocardial Infarction (TIMI) risk score.** The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the Legislation Act 2003. The TIMI risk score is a prognostication scheme that categorises a patient's risk of death and ischemic events in patients with unstable angina or non-ST-segment elevation myocardial infarction.	The TIMI risk score is available for download for free from the Journal of the American Medical Association website https://jamanetwork.com/journals/jama/fullarticle/192996
Cetuximab Panitumumab Pembrolizumab	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status.** World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status. The document is incorporated as	The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research

in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the Legislation Act 2003. The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themself, daily activity, and physical ability (walking, working, etc.).	Group website: https://ecog-acrin.org/resources/ecog-performance-status

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 2021 (No. 7)

(PB 74 of 2021)

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 2021 (No. 7)* 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).

The amendments in Schedule 1 to this Instrument rectify the inadvertent removal of authorised prescribers for extemporaneously-prepared pharmaceutical benefits by the *National Health Legislation Amendment (Listing of Pharmaceutical Benefits for Supply Only) Instrument 2020* on 1 November 2020. Consistent with the arrangements under the Principal Instrument before 1 November 2020, the amendments in Schedule 1 authorise medical pracititioners to prescribe extemporaneously-prepared pharmaceutical benefits.

The amendments in Schedule 2 involve the addition of listed drugs, the addition of forms of listed drugs, the addition of brands, the addition and alteration of responsible person codes for brands of pharmaceutical benefits, the addition of 7 brands of pharmaceutical items to supply only status, the deletion of listed drugs from the list of extemporaneously-prepared pharmaceutical benefits, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the PBS.

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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