EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2021 (No. 3)

PB 22 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).

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).

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.

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 changes the date of repeal of subsection 10A(3) from 1 April 2021 to 1 January 2022. This amendment ensures that temporary measures for modified prescription circumstances during the COVID-19 pandemic remain in effect during the current health pandemic.

Schedule 1 to this Instrument provides for the addition of the listed drugs fulvestrant, indacaterol with glycopyrronium and mometasone and romosozumab and forms of the listed drugs adalimumab and sertraline to the Schedule of Pharmaceutical Benefits. It also provides for the deletion of the listed drug nadroparin and forms of the listed drugs cefuroxime and paracetamol from the PBS. In addition, it provides for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs adalimumab, amino acid formula with vitamins and minerals without lysine and low in tryptophan, apomorphine, baricitinib, certolizumab pegol, dupilumab, golimumab, ipilimumab, nivolumab, ribociclib, secukinumab and teriparatide.

Schedule 1 to this Instrument also provides for the following changes:

- the addition of 38 brands and deletion of 10 brands of existing pharmaceutical items;
- the alteration of a brand name for 1 existing brand of a pharmaceutical item;
- the addition of 2 maximum quantity and number of number of repeats for an existing brand of a pharmaceutical item;

- the addition of a pack quantity for an existing brand of a pharmaceutical item;
- the deletion of a pack quantity for 2 existing brands of a pharmaceutical item;
- the addition of 1 responsible person code to the list of responsible persons and the alteration of 1 responsible person name; and
- the addition of 10 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.

This Instrument commences on 1 April 2021.

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. 3)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2021 (No. 3)* and may also be cited as PB 22 of 2021.

Section 2 Commencement

This section provides that this Instrument commences on 1 April 2021.

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 the addition and deletion of drugs, the addition and deletion of forms of drugs, the addition and deletion of brands, the alteration of a brand name, the addition of a responsible person code and alteration of a responsible person name, the addition of maximum quantities and numbers of repeats, the addition and deletion of pack quantities, the addition of brands of pharmaceutical items to supply only status 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 THIS INSTRUMENT

Listed Drugs Added

Listed Drug

Fulvestrant

Indacaterol with glycopyrronium and mometasone

Romosozumab

Listed Drugs Deleted

Listed Drug

Nadroparin

Forms Added

Listed Drug	***Form***
Adalimumab	Injection 20 mg in 0.2 mL pre-filled syringe
	Injection 40 mg in 0.4 mL pre-filled pen

	Injection 40 mg in 0.4 mL pre-filled syringe
	Injection 80 mg in 0.8 mL pre-filled pen
	Injection 80 mg in 0.8 mL pre-filled syringe
Sertraline	Tablet 50 mg (as hydrochloride) (USP)
	Tablet 100 mg (as hydrochloride) (USP)

Forms Deleted

Listed Drug	*Form*
Cefuroxime	Powder for oral suspension 125 mg (as axetil) per 5 mL, 70 mL
Paracetamol	Suppositories 500 mg, 24

Brands Added

Listed Drug	*Form and Brand*
Buprenorphine	Transdermal patch 25 mg (*Buprenorphine Sandoz)*
	Transdermal patch 30 mg *(Buprenorphine Sandoz)*
	Transdermal patch 40 mg (*Buprenorphine Sandoz)*
Cabazitaxel	Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent *(Cabazitaxel Juno)*
Cinacalcet	Tablet 30 mg (as hydrochloride) *(Cinacalcet Mylan)*
	Tablet 60 mg (as hydrochloride) *(Cinacalcet Mylan)*
	Tablet 90 mg (as hydrochloride) *(Cinacalcet Mylan)*
Erlotinib	Tablet 25 mg (as hydrochloride) *(Erlotinib Sandoz)*
	Tablet 100 mg (as hydrochloride) *(Erlotinib Sandoz)*
	Tablet 150 mg (as hydrochloride) *(Erlotinib Sandoz)*
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate) *(APO-Esomeprazole; Esopreze)*
	Tablet (enteric coated) 40 mg (as magnesium trihydrate) *(APO-Esomeprazole; Esopreze)*
Fluticasone propionate	Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) *(Axotide Junior)*
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses *(Axotide Junior Accuhaler)*
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses *(Axotide Accuhaler)*

Fluticasone propionate with salmeterol	Pressurised inhalation containing fluticasone propionate 50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) *(PAVTIDE MDI 50/25)*
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses *(PAVTIDE ACCUHALER 100/50)*
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses *(PAVTIDE ACCUHALER 250/50)*
	Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses *(PAVTIDE ACCUHALER 500/50)*
Gabapentin	Capsule 100 mg *(APX-Gabapentin)*
	Capsule 300 mg *(APX-Gabapentin)*
	Capsule 400 mg *(APX-Gabapentin)*
Ganirelix	Injection 250 micrograms (as acetate) in 0.5 mL pre-filled syringe *(GANIRELIX SUN)*
Irinotecan	I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in 25 mL *(Irinotecan Accord)*
Nebivolol	Tablet 1.25 mg (as hydrochloride) *(Nepiten)*
	Tablet 5 mg (as hydrochloride) *(Nepiten)*
	Tablet 10 mg (as hydrochloride) *(Nepiten)*
Omeprazole	Tablet 20 mg *(Maxor EC Tabs)*
Posaconazole	Tablet (modified release) 100 mg *(Posaconazole ARX)*
Rosuvastatin	Tablet 5 mg (as calcium) *(Rosuvastatin Lupin)*
	Tablet 10 mg (as calcium) *(Rosuvastatin Lupin)*
	Tablet 20 mg (as calcium) *(Rosuvastatin Lupin)*
	Tablet 40 mg (as calcium) *(Rosuvastatin Lupin)*
Tenofovir	Tablet containing tenofovir disoproxil fumarate 300 mg *(Tenofovir Sandoz)*
Teriflunomide	Tablet 14 mg *(Terimide)*
Zoledronic acid	Solution for I.V. infusion 5 mg (as monohydrate) in 100 mL *(Zoledronic Acid SUN)*

Brands Deleted

Listed Drug	***Form and Brand***
Captopril	Tablet 25 mg *(Zedace)*

	Tablet 50 mg (*Zedace)*
Erlotinib	Tablet 25 mg (as hydrochloride) *(Tarceva)*
	Tablet 100 mg (as hydrochloride) *(Tarceva)*
	Tablet 150 mg (as hydrochloride) *(Tarceva)*
Rituximab	Solution for I.V. infusion 100 mg in 10 mL *(Mabthera)*
	Solution for I.V. infusion 500 mg in 50 mL *(Mabthera)*
Somatropin	Solution for injection 5 mg (15 i.u.) in 1.5 mL cartridge (with preservative) *(Norditropin SimpleXx)*
	Solution for injection 10 mg (30 i.u.) in 1.5 mL cartridge (with preservative) *(Norditropin SimpleXx)*
	Solution for injection 15 mg (45 i.u.) in 1.5 mL cartridge (with preservative) *(Norditropin SimpleXx)*

Alteration of Brand Name

Listed Drug	***Form***	***Brand Name***
Phenobarbital	Injection 200 mg (as sodium) in 1 mL	***From:*** Fawns and McAllan Proprietary Limited ***To:*** Phenobarbitone Injection (Aspen Pharmacare Australia Pty Ltd)

Alteration of Form

Listed Drug	***Form***
Adalimumab	**From:** Injection 40 mg in 0.8 mL pre-filled pen, 4 **To:** Injection 40 mg in 0.8 mL pre-filled pen
	From: Injection 40 mg in 0.8 mL pre-filled pen, 6 **To:** Injection 40 mg in 0.8 mL pre-filled pen
	From: Injection 40 mg in 0.8 mL pre-filled syringe, 6 **To:** Injection 40 mg in 0.8 mL pre-filled pen

Addition of Maximum Quantity and Number of Repeats

Listed Drug	***Form***	***Brand Name***	***Maximum Quantity***	***Number of Repeats***
Secukinumab	Injection 150 mg in 1 mL pre-filled pen	Cosentyx	1	0
		Cosentyx	5	0

Addition of Responsible Person Code

Responsible Person and Code

Arrotex Pharmaceuticals Pty Ltd (*XT*)

Alteration of Responsible Person Name

From:	***To:***
A. Menarini Australia Pty Limited (*FK*)	A.Menarini Australia Pty Limited (*FK*)

Addition of Pack Quantity

Listed Drug	***Form***	***Brand Name***	***Pack Quantity***
Oxycodone	Capsule containing oxycodone hydrochloride 5 mg	OxyNorm	10

Deletion of Pack Quantity

Listed Drug	***Form***	***Brand Name***	***Pack Quantity***
Oxycodone	Capsule containing oxycodone hydrochloride 5 mg	Oxycodone BNM	20
		OxyNorm	20

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Adalimumab

Amino acid formula with vitamins and minerals without lysine and low in tryptophan

Apomorphine

Baricitinib

Certolizumab pegol

Dupilumab

Golimumab

Ipilimumab

Nivolumab

Ribociclib

Secukinumab

Teriparatide

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*
Nadroparin	Injection containing nadroparin calcium (1,900 I.U. anti-Xa) in 0.2 mL pre-filled syringe *(Fraxiparine)*
	Injection containing nadroparin calcium (2,850 I.U. anti-Xa) in 0.3 mL pre-filled syringe *(Fraxiparine)*
	Injection containing nadroparin calcium (3,800 I.U. anti-Xa) in 0.4 mL pre-filled syringe *(Fraxiparine)*
	Injection containing nadroparin calcium (5,700 I.U. anti-Xa) in 0.6 mL pre-filled syringe *(Fraxiparine)*
	Injection containing nadroparin calcium (7,600 I.U. anti-Xa) in 0.8 mL pre-filled syringe *(Fraxiparine)*
	Injection containing nadroparin calcium (9,500 I.U. anti-Xa) in 1 mL pre-filled syringe *(Fraxiparine)*
	Injection containing nadroparin calcium (11,400 I.U. anti-Xa) in 0.6 mL pre-filled syringe *(Fraxiparine Forte)*
	Injection containing nadroparin calcium (15,200 I.U. anti-Xa) in 0.8 mL pre-filled syringe *(Fraxiparine Forte)*
	Injection containing nadroparin calcium (19,000 I.U. anti-Xa) in 1 mL pre-filled syringe *(Fraxiparine Forte)*
Paracetamol	Suppositories 500 mg, 24 *(Panadol)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Adalimumab	**Paediatric Ulcerative Colitis Activity Index (PUCAI).** 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 PUCAI is a standard medical diagnostic tool used to measure disease activity in children and adolescents with Ulcerative Colitis through the evaluation of symptoms.	The PUCAI is available for download for free from the Inflammatory Bowel Diseases Journal via the Oxford University Press website https://academic.oup.com/ibdjournal/article/15/8/1218/4643533
	Crohn Disease Activity Index (CDAI). Crohn's Disease Activity Index (CDAI). 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 Crohn's Disease Activity Index (CDAI) is a research tool used to quantify the symptoms of patients with Crohn's disease.	The CDAI is available for dowload for free from the Gastroenterology journal website www.gastrojournal.org/article/S0016-5085(76)80163-1/abstract NOTE: a CDAI score calculation form is included in the Services Australia application form.

	Mayo clinic score and partial Mayo clinic 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 Mayo clinic score and the partial Mayo clinic score (an abbreviated form of the Mayo clinic score) are medical diagnostic tools used to measure disease activity, in a standardised way, in Ulcerative Colitis through the evaluation of symptoms.	The Mayo clinic score and the partial Mayo clinic score are available to download for free from the Inflammatory Bowel Diseases Journal via the Oxford University Press website https://academic.oup.com/ibdjournal/article/14/12/1660/4654949?login=true
Certolizumab pegol Golimumab Secukinumab	**Bath Ankylosing Spondylitis Disease Activity Index (BASDAI).** Bath Ankylosing Spondylitis Disease Activity Index (BASDAI). 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 BASDAI is a widely used tool that enables measurement and evaluation of the level of disease activity in Ankylosing Spondylitis.	The BASDAI is available for download for free from the Services Australia website www.servicesaustralia.gov.au
Certolizumab pegol Golimumab Secukinumab	**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
Golimumab	**Mayo clinic score and partial Mayo clinic 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 Mayo clinic score and the partial Mayo clinic score (an abbreviated form of the Mayo clinic score) are medical diagnostic tools used to measure disease activity, in a standardised way, in Ulcerative Colitis through the evaluation of symptoms.	The Mayo clinic score and the partial Mayo clinic score are available to download for free from the Inflammatory Bowel Diseases Journal via the Oxford University Press website https://academic.oup.com/ibdjournal/article/14/12/1660/4654949?login=true
Dupilumab	**Asthma Control Questionnaire (ACQ-5) and/or Asthma Control Questionnaire interviewer administered version (ACQ-IA).** 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 ACQ-5 and the ACQ-IA are widely used tools for measuring how well a patient's asthma symptoms are being controlled.	Prescribers can contact the suppliers of these asthma medications directly to obtain free copies of the ACQ calculation sheets. Contact details for the suppliers can be found online at www.pbs.gov.au
	Dermatology Life Quality Index (DLQI). The document is incorporated as in force on the day	The DLQI is available for download for free from the Cardiff

	this Instrument takes effect, pursuant to paragraph 14(1)(b) of the Legislation Act 2003. The DLQI is designed to measure the health-related quality of life of adult patients suffering from a skin disease.	University website: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index
	Eczema Area and Severity Index (EASI). 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 EASI is a validated scoring system that grades the physical signs of atopic dermatitis/eczema.	Instructions on the use of the Eczema Area and Severity Index and copyright details are available for download for free from the Dupixent (UK) website: https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf
	Physicians Global Assessment (PGA) (5-point scale). 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 PGA is a 5-point scale that measures the severity of atopic dermatitis.	The Physician's Global Assessment is not publicly available, but can be obtained free of charge from Sanofi Medical Information, along with instructions on the use of the Physician's Global Assessment (5-point scale) by phoning 1800 818 806 or email MedInfo.Australia@sanofi.com.
Ipilimumab Nivolumab Ribociclib	**World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status.** World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status. 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 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.).	The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research 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. 3)

(PB 22 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. 3)* 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 involve the addition and deletion of drugs, the addition and deletion of forms of drugs, the addition and deletion of brands, the alteration of a brand name, the addition of a responsible person code and alteration of a responsible person name, the addition of maximum quantities and numbers of repeats, the addition and deletion of pack quantities, the addition of brands of pharmaceutical items to supply only status and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme.

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.

Thea Connolly
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health