

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 6)

PB 54 of 2023

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 for the purposes of the Pharmaceutical Benefits Scheme (PBS), and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the Schedule of Pharmaceutical Benefits (the PBS Schedule) 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

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.

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.

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)).

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 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 to this Instrument provides for the addition to the PBS Schedule of the drugs avatrombopag and finerenone, and forms of the listed drugs acalabrutinib and pemetrexed. It also provides for the alteration of form names and pack quantities for the listed drugs budesonide with formoterol, and methadone, and for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abatacept, adalimumab, baricitinib, buprenorphine, buprenorphine with naloxone, certolizumab pegol, choriogonadotropin alfa, etanercept, fluticasone propionate, golimumab, methadone, nirmatrelvir and ritonavir, tocilizumab, tofacitinib, upadacitinib, and zanubrutinib.

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

- the addition of 18 brands of existing pharmaceutical items
- the deletion of 19 brands of existing pharmaceutical items
- the deletion of 9 pharmaceutical items covered under Supply Only arrangements.

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 July 2023.

This Instrument is a legislative instrument for the purposes of the *Legislation Act 2003*.

PROVISION-BY-PROVISION DESCRIPTION OF NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 6)

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 6)* and may also be cited as PB 54 of 2023.

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, Schedule 1 to the Instrument commences on 1 July 2023.

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.

Schedule 1 Amendments

The amendments in Schedule 1 involve the addition of listed drugs, the addition of forms of listed drugs, the alteration of form names and pack quantities, the addition and deletion of brands, the deletion of benefits covered under Supply Only arrangements, 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 1 OF THIS INSTRUMENT**

Drugs Added

Listed Drug

Avatrombopag

Finerenone

Forms Added

Listed Drug

Form

Acalabrutinib Tablet 100 mg

Pemetrexed Solution concentrate for I.V. infusion 100 mg (as disodium) in 4 mL
 Solution concentrate for I.V. infusion 500 mg (as disodium) in 20 mL
 Solution concentrate for I.V. infusion 1 g (as disodium) in 40 mL

Alteration of Form Name and Pack Quantity

<i>Listed Drug</i>	<i>Form</i>	<i>Brand name</i>	<i>Pack Quantity</i>
Budesonide with formoterol	From: Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2	<i>BiResp Spiromax</i>	From: 1
		<i>Duo BiResp Spiromax</i>	
	To: Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses	<i>BiResp Spiromax</i>	To: 2
		<i>Duo BiResp Spiromax</i>	
Methadone	From: Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L	<i>Aspen Methadone Syrup</i>	From: 1
		<i>Biodone Forte</i>	
	To: Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 1 L bottle, 1 mL	<i>Aspen Methadone Syrup</i>	To: 1000
		<i>Biodone Forte</i>	
	From: Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL	<i>Aspen Methadone Syrup</i>	From: 1
		<i>Biodone Forte</i>	
	To: Oral liquid containing methadone hydrochloride 25 mg per 5 mL in 200 mL bottle, 1 mL	<i>Aspen Methadone Syrup</i>	To: 200
		<i>Biodone Forte</i>	

Brands Added

<i>Listed Drug</i>	<i>Form and Brand</i>
Azacitidine	Powder for injection 100 mg (<i>Azacitidine Sandoz</i>)
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 (<i>Rilast TURBUHALER 200/6</i>)
Candesartan	Tablet containing candesartan cilexetil 4 mg (<i>BTC Candesartan</i>)
	Tablet containing candesartan cilexetil 8 mg (<i>BTC Candesartan</i>)
	Tablet containing candesartan cilexetil 16 mg (<i>BTC Candesartan</i>)
	Tablet containing candesartan cilexetil 32 mg (<i>BTC Candesartan</i>)
Ezetimibe and rosuvastatin	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 10 mg (as calcium) (<i>Pharmacor Ezetimibe Rosuvastatin Composite Pack</i>)
	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 20 mg (as calcium) (<i>Pharmacor Ezetimibe Rosuvastatin Composite Pack</i>)

	Pack containing 30 tablets ezetimibe 10 mg and 30 tablets rosuvastatin 40 mg (as calcium) (<i>Pharmacor Ezetimibe Rosuvastatin Composite Pack</i>)
Fingolimod	Capsule 500 micrograms (as hydrochloride) (<i>FINGOLIS</i>)
Irbesartan	Tablet 75 mg (<i>Noumed Irbesartan</i>)
	Tablet 150 mg (<i>Noumed Irbesartan</i>)
	Tablet 300 mg (<i>Noumed Irbesartan</i>)
Lamivudine with zidovudine	Tablet 150 mg-300 mg (<i>Lamivudine/Zidovudine Viatris 150/300</i>)
Mirtazapine	Tablet 15 mg (<i>Blooms The Chemist Mirtazapine</i>)
	Tablet 30 mg (<i>Blooms The Chemist Mirtazapine</i>)
	Tablet 45 mg (<i>Blooms The Chemist Mirtazapine</i>)
Paroxetine	Tablet 20 mg (as hydrochloride) (<i>Noumed Paroxetine</i>)

Brands Deleted

Listed Drug	Form and Brand
Alendronic acid with colecalciferol	Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol (<i>Alendronate plus D3-DRLA</i>)
	Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol (<i>Alendronate plus D3-DRLA</i>)
Azathioprine	Tablet 25 mg (<i>Azathioprine GH</i>)
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate) (<i>Esomeprazole Sandoz; Esomeprazole SZ</i>)
	Tablet (enteric coated) 40 mg (as magnesium trihydrate) (<i>Esomeprazole Sandoz; Esomeprazole SZ</i>)
Lamotrigine	Tablet 25 mg (<i>Lamotrigine Sandoz</i>)
	Tablet 50 mg (<i>Lamotrigine Sandoz</i>)
	Tablet 100 mg (<i>Lamotrigine Sandoz</i>)
	Tablet 200 mg (<i>Lamotrigine Sandoz</i>)
Metformin	Tablet containing metformin hydrochloride 1 g (<i>Sandoz Metformin</i>)
Mirtazapine	Tablet 15 mg (orally disintegrating) (<i>Mirtazapine Sandoz ODT 15</i>)
	Tablet 30 mg (orally disintegrating) (<i>Mirtazapine Sandoz ODT 30</i>)
	Tablet 45 mg (orally disintegrating) (<i>Mirtazapine Sandoz ODT 45</i>)
Oxycodone	Capsule containing oxycodone hydrochloride 10 mg (<i>Oxycodone BNM</i>)

Pravastatin	Tablet containing pravastatin sodium 80 mg (<i>Pravastatin Sandoz</i>)
Rizatriptan	Tablet (orally disintegrating) 10 mg (as benzoate) (<i>Rizatriptan-AU</i>)
Telmisartan	Tablet 40 mg (<i>Telmisartan GH</i>)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Abatacept	Fluticasone propionate
Adalimumab	Golimumab
Baricitinib	Methadone
Buprenorphine	Nirmatrelvir and ritonavir
Buprenorphine with naloxone	Tocilizumab
Certolizumab pegol	Tofacitinib
Choriogonadotropin alfa	Upadacitinib
Etanercept	Zanubrutinib

Supply Only – Deletions

Listed Drug

Form and Brand

Budesonide with formoterol	Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2 (<i>Symbicort Turbuhaler 400/12</i>)
Ertugliflozin with metformin	Tablet containing 2.5 mg ertugliflozin with 500 mg metformin hydrochloride (<i>Segluromet 2.5/500</i>)
	Tablet containing 2.5 mg ertugliflozin with 1 g metformin hydrochloride (<i>Segluromet 2.5/1000</i>)
	Tablet containing 7.5 mg ertugliflozin with 500 mg metformin hydrochloride (<i>Segluromet 7.5/500</i>)
	Tablet containing 7.5 mg ertugliflozin with 1 g metformin hydrochloride (<i>Segluromet 7.5/1000</i>)
Nicotine	Gum 2 mg (<i>Nicotinell</i>)
	Gum 4 mg (<i>Nicotinell</i>)
	Lozenge 2 mg (<i>Nicotinell</i>)
	Lozenge 4 mg (<i>Nicotinell</i>)

Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Adalimumab Etanercept Tocilizumab	<p>Approved Product Information/Australian Product Information/TGA-approved Product Information.</p> <p>The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>This document provides health professionals with a summary of the scientific information relevant to the safe and effective use of a prescription medicine.</p>	<p>TGA-approved Product Information is available for download for free from the TGA website: https://www.tga.gov.au/product-information-0</p>

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 2023 (No. 6) **(PB 54 of 2023)**

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 2023 (No. 6)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) 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).

Human rights implications

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

The Right to Social Security

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

The Right to Health

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

Analysis

The Instrument advances the right to health and the right to social security by providing new drugs, new forms and brands of existing listed drugs, and ensuring the deletion of brands of listed drugs does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (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 Schedule are evidence-based. The Instrument includes the addition of two new drugs, the addition of four new forms of existing drugs, and the addition of 18 new brands across 18 existing forms, which allows for greater patient access to these drugs.

When a sponsor submits a request to delist a drug from the PBS, subsection 101(4AAB) of the *National Health Act 1953* requires that the Minister or their delegate obtain advice from the Pharmaceutical Benefits Advisory Committee (PBAC), an independent and expert advisory body, before varying or revoking declarations under subsection 85(2) so as to delist the drug. In these instances, one of the matters which the PBAC provides advice on is whether the delisting of a drug will result in an unmet clinical need for patients. The PBAC also considers whether the delisting of a form of a drug will result in an unmet clinical need for patients.

Written advice from the PBAC is tabled with the monthly amendments to the Principal Instrument. An unmet clinical need would arise when a currently treated patient population would be left without treatment options once a delisting occurs. Alternative treatment options could include using a different: form, strength or drug. The PBAC considered the delisting of drugs and forms of drugs in the abovementioned instruments, would not result in an unmet clinical need, except where indicated for a particular drug or form of drug below. Where the PBAC has identified an unmet clinical need, a Supply Only period has been/will be instituted as outlined below to allow opportunity for patients to transition to an alternative treatment option. The delisting of these items will not affect access to the drugs (or an alternative treatment if required), as affected patients will be able to access alternative medicines through the PBS, and the delisting is unlikely to have an effect on the amount patients pay for those drugs, as co-payment amounts are capped, ensuring their rights to social security are maintained. From 1 January 2023, these amounts are \$30.00 for general patients and \$7.30 for concession card holders.

Where there are many brands of a listed drug and form, then the delisting of one brand will not adversely affect members of the public as they will be able to obtain any of the other equivalent brands. The delisting of brands in this Instrument will not affect access to the drugs, as affected patients will be able to access equivalent brands, at the same cost. Consequently, the brand delistings in this instrument do not result in an unmet clinical need. Note that delisting of maximum quantities, number of repeats, and pack sizes are equivalent to brand delistings.

The drug ertugliflozin with metformin (Segluromet), was requested to be delisted from the Pharmaceutical Benefits Scheme (PBS) by the sponsor. The PBAC noted the range of alternatives on the Schedule and also that the two agents would remain listed as individual products. The PBAC advised the delisting of these products would not result in an unmet clinical need. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug nicotine in the forms gum 2 mg (Nicotinell), gum 4 mg (Nicotinell), lozenge 2 mg (Nicotinell), and lozenge 4 mg (Nicotinell) was requested to be delisted from the PBS by the sponsor. The PBAC noted that there are no suitable alternatives on the PBS as these are acute dosing forms of nicotine and advised the delisting of these products may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor chose to proceed with the delisting. These items were available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre-existing valid prescription to access these items pending transition to an alternative treatment option.

Conclusion

This Instrument is compatible with human rights because it advances the protection of human rights.

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