EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 1)

PB 1 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 *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 to this Instrument provides for the addition to the PBS Schedule of the listed drug opicapone, and the addition of a form of the listed drug beclometasone with formoterol. It also provides for the deletion of the listed drug exenatide and for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs acalabrutinib, molnupiravir, nirmatrelvir and ritonavir, romosozumab, and upadacitinib.

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

- the addition of 43 brands of existing pharmaceutical items;
- the deletion of 4 brands of existing pharmaceutical items;
- the alteration of form name for 4 existing pharmaceutical items;
- the alteration of a brand name for 1 existing pharmaceutical item;
- the deletion of a pack quantity for 1 existing pharmaceutical item;
- the addition of 2 responsible persons to the list of responsible persons; and
- the deletion of 4 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 February 2023.

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 2023 (No. 1)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 1)* and may also be cited as PB 1 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 February 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 and deletion of listed drugs, the addition of a form of a listed drug, the addition and deletion of brands, the alteration of form names for pharmaceutical items, the alteration of a brand name, the deletion of a pack quantity for a brand of pharmaceutical benefit, the addition of responsible persons to the list of responsible persons, 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

Drug Added

Listed Drug

Opicapone

Drug Deleted

Listed Drug

Exenatide

Form Added

Listed Drug	***Form***
Beclometasone with formoterol	Pressurised inhalation containing beclometasone dipropionate 200 micrograms and formoterol fumarate dihydrate 6 micrograms per dose, 120 doses

Brands Added

Listed Drug	*Form and Brand*
Acarbose	Tablet 100 mg *(Acarbose Viatris)*
Ambrisentan	Tablet 10 mg *(Ambrisentan Viatris)*
Carbimazole	Tablet 5 mg *(WP Carbimazole)*
Cinacalcet	Tablet 60 mg (as hydrochloride) *(Cinacalcet Viatris)*
Dimethyl fumarate	Capsule (modified release) 120 mg *(APO-DIMETHYL FUMARATE; Dimethyl Fumarate MSN)*
	Capsule (modified release) 240 mg *(APO-DIMETHYL FUMARATE; Dimethyl Fumarate MSN)*
Domperidone	Tablet 10 mg *(APO-DOMPERIDONE)*
Fingolimod	Capsule 500 micrograms (as hydrochloride) *(Fynod)*
Flucloxacillin	Capsule 250 mg (as sodium monohydrate) *(Flopen Viatris)*
	Capsule 500 mg (as sodium monohydrate) *(Flopen Viatris)*
Lenalidomide	Capsule 5 mg *(Cipla Lenalidomide; Lenalide; Lenalidomide Dr.Reddy's; Lenalidomide Sandoz; Lenalidomide-Teva)*
	Capsule 10 mg *(Cipla Lenalidomide; Lenalide; Lenalidomide Dr.Reddy's; Lenalidomide Sandoz; Lenalidomide-Teva)*
	Capsule 15 mg *(Cipla Lenalidomide; Lenalide; Lenalidomide Dr.Reddy's; Lenalidomide Sandoz; Lenalidomide-Teva)*
	Capsule 25 mg *(Cipla Lenalidomide; Lenalide; Lenalidomide Dr.Reddy's; Lenalidomide Sandoz; Lenalidomide-Teva)*
Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, 15 mL *(Optix)*
Sitagliptin	Tablet 25 mg *(Sitaglo)*
	Tablet 50 mg *(Sitaglo)*
	Tablet 100 mg *(Sitaglo)*
Temozolomide	Capsule 5 mg *(Temizole 5)*
Tenecteplase	Powder for injection 50 mg with solvent (s19A) *(TNKase (Canada) Medsurge Healthcare Pty Ltd)*
Tenofovir with emtricitabine and efavirenz	Tablet containing tenofovir disoproxil maleate 300 mg with emtricitabine 200 mg and efavirenz 600 mg *(Tenofovir Disoproxil Emtricitabine Efavirenz Viatris 300/200/600)*
Tetrabenazine	Tablet 25 mg *(Tetrabenazine SUN)*

Tobramycin	Injection 80 mg in 2 mL *(Tobramycin Viatris)*
Vancomycin	Capsule 125 mg (125,000 I.U.) (as hydrochloride) *(Vancomycin BNM 125mg)*
	Capsule 250 mg (250,000 I.U.) (as hydrochloride) *(Vancomycin BNM 250mg)*

Brands Deleted

Listed Drug	***Form and Brand***
Nitrofurantoin	Capsule 50 mg *(ARX-Nitrofurantoin)*
	Capsule 100 mg *(ARX-Nitrofurantoin)*
Salbutamol	Nebuliser solution 5 mg (as sulfate) in 2.5 mL single dose units, 30 *(APO-Salbutamol)*
Temozolomide	Capsule 5 mg *(Temozolomide Alphapharm)*

Alteration of Form Name

Listed Drug	***Form***
Morphine	***From:*** Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 200 mL ***To:*** Oral solution containing morphine hydrochloride trihydrate 2 mg per mL, 1 mL
	From: Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 200 mL ***To:*** Oral solution containing morphine hydrochloride trihydrate 5 mg per mL, 1 mL
	From: Oral solution containing morphine hydrochloride trihydrate 10 mg per mL, 200 mL ***To:*** Oral solution containing morphine hydrochloride trihydrate 10 mg per mL,1 mL
Oxycodone	***From:*** Oral solution containing oxycodone hydrochloride 1 mg per mL, 250 mL ***To:*** Oral solution containing oxycodone hydrochloride 1 mg per mL, 1 mL

Alteration of Brand Name

Listed Drug	***Form***	***Brand Name***
Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Danish 1331 strain	Single dose pack containing powder for irrigation 30 mg, 4 vials	***From:*** *BCG Culture SSI* ***To:*** *VesiCulture*

Deletion of Pack Quantity

Listed Drug	***Form***	***Brand Name***	***Pack Quantity***
Sumatriptan	Tablet (fast disintegrating) 50 mg (as succinate)	*Imigran FDT*	2

Addition of Responsible Person Code

Medtas Pty Ltd *(TN)*

MAXX PHARMA PTY LTD *(XY)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Acalabrutinib

Molnupiravir

Nirmatrelvir and ritonavir

Romosozumab

Upadacitinib

Supply Only – Deletions

Listed Drug	*Form and Brand*
Amino acid formula with vitamins and minerals without phenylalanine	Oral liquid 130 mL, 30 (PKU Air 15) *(PKU Air 15)*
Cromoglycic acid	Pressurised inhalation containing sodium cromoglycate 1 mg per dose, 200 doses (CFC-free formulation) *(Intal CFC-Free)*
Glycomacropeptide and essential amino acids with vitamins and minerals	Sachets containing oral powder 51 g, 30 (PKU Bettermilk Lite) *(PKU Bettermilk Lite)*
Ledipasvir with sofosbuvir	Tablet containing 90 mg ledipasvir with 400 mg sofosbuvir *(Harvoni)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Romosozumab	**Approved Product Information/Australian Product Information/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

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. 1)

(PB 1 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. 1)* (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, and new forms and brands of existing listed drugs, and ensuring the deletion of listed drugs and 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 one new drug, one new form of an existing drug and the addition of 43 new brands across 25 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. The delisting of these items will not affect access to the drugs, 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 amino acid formula with vitamins and minerals without phenylalanine in the form oral liquid 130 mL, 30 (PKU Air 15) was requested to be delisted from the PBS by the sponsor due to very few sales of this product. The PBAC noted the low number of services and that the sponsor had contacted health care professionals to advise of the delisting so that patients could transfer to an alternative product. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 2 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug cromoglycic acid in the form pressurised inhalation containing sodium cromoglycate 1 mg per dose, 200 doses (CFC-free formulation) (Intal CFC-Free) was requested to be delisted from the PBS by the sponsor due to discontinuation of the product. The PBAC considered that the other PBS listed forms and strengths of inhaled corticosteroids and montelukast would be suitable alternatives. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug exenatide in the forms injection solution 5 micrograms per dose in pre-filled pen, 60 doses, and injection solution 10 micrograms per dose in pre-filled pen, 60 doses (Byetta) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, available clinical alternatives and sponsor's intent to discontinue supply of the product. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

The drug glycomacropeptide and essential amino acids with vitamins and minerals in the form sachets containing oral powder 51 g, 30 (PKU Bettermilk Lite) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation and that there are several other PBS listed suitable alternatives available. The PBAC advised that the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 6 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug ledipasvir with sofosbuvir in the form tablet containing 90 mg ledipasvir with 400 mg sofosbuvir (Harvoni) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low utilisation, current role in therapy and available clinical alternatives. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item was available on the PBS Schedule under Supply Only arrangements for a period of up to 6 months, allowing patients with a pre-existing valid prescription to access this item 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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