

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 13)

PB 128 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(4ACA) 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 forms of the listed drugs benzathine benzylpenicillin, hydromorphone, lumacaftor with ivacaftor, and pomalidomide. It also provides for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs acalabrutinib, ibrutinib, obinutuzumab, olaparib, pembrolizumab, ustekinumab, venetoclax, and zanubrutinib.

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

- the addition of 19 brands of existing pharmaceutical items
- the deletion of 66 brands of existing pharmaceutical items
- the alteration of a manufacturer code for existing pharmaceutical items
- the addition of 5 pharmaceutical items covered under Supply Only arrangements
- the deletion of a pharmaceutical item 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 January 2024.

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. 13)

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 13)* and may also be cited as PB 128 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 January 2024.

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

This section 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 forms of listed drugs, the addition and deletion of brands, the alteration of a manufacturer code for brands of pharmaceutical items, the addition and deletion of pharmaceutical 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**

Forms Added

<i>Listed Drug</i>	<i>Form</i>
Benzathine benzylpenicillin	Powder for injection 1,200,000 units with diluent 5 mL (S19A)
Hydromorphone	Oral solution containing hydromorphone hydrochloride 1mg per mL, 1mL (S19A)
Lumacaftor with ivacaftor	Sachet containing granules, lumacaftor 75 mg and ivacaftor 94 mg
Pomalidomide	Capsule 1 mg Capsule 2 mg

Brands Added

<i>Listed Drug</i>	<i>Form and Brand</i>
Abacavir with lamivudine	Tablet containing abacavir 600 mg (as sulfate) with lamivudine 300 mg (<i>Abacavir/Lamivudine Viatris</i>)

Adalimumab	Injection 40 mg in 0.4 mL pre-filled pen (<i>Adalicip</i>) Injection 40 mg in 0.4 mL pre-filled syringe (<i>Adalicip</i>)
Dabigatran etexilate	Capsule 75 mg (as mesilate) (<i>ARX-Dabigatran</i>) Capsule 110 mg (as mesilate) (<i>ARX-Dabigatran</i>) Capsule 150 mg (as mesilate) (<i>ARX-Dabigatran</i>)
Deferasirox	Tablet, dispersible, 125 mg (<i>Pharmacor Deferasirox</i>) Tablet, dispersible, 250 mg (<i>Pharmacor Deferasirox</i>) Tablet, dispersible, 500 mg (<i>Pharmacor Deferasirox</i>)
Dimethyl fumarate	Capsule (modified release) 240 mg (<i>Trazent</i>)
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate) (<i>Esomeprazole Viatris</i>) Tablet (enteric coated) 40 mg (as magnesium trihydrate) (<i>Esomeprazole Viatris</i>)
Metoclopramide	Injection containing 10 mg metoclopramide hydrochloride (as monohydrate) in 2 mL (<i>METOCLOPRAMIDE INJECTION BP</i>)
Pirfenidone	Tablet 267 mg (<i>Pirfenidet</i>) Tablet 801mg (<i>Pirfenidet</i>)
Ramipril	Tablet 1.25 mg (<i>Ramipril Viatris</i>)
Sitagliptin with metformin	Tablet containing 50 mg sitagliptin with 500 mg metformin hydrochloride (<i>SITAGLIPTIN/METFORMIN 50/500 SUN</i>) Tablet containing 50 mg sitagliptin with 850 mg metformin hydrochloride (<i>SITAGLIPTIN/METFORMIN 50/850 SUN</i>) Tablet containing 50 mg sitagliptin with 1000 mg metformin hydrochloride (<i>SITAGLIPTIN/METFORMIN 50/1000 SUN</i>)

Brands Deleted

Listed Drug	Form and Brand
Aciclovir	Tablet 200 mg (<i>GenRx Aciclovir</i>)
Bortezomib	Powder for injection 3.5 mg (<i>Bortezomib-AFT</i>)
Cefaclor	Powder for oral suspension 250 mg (as monohydrate) per 5 mL, 75 mL (<i>APO-Cefaclor</i>) Tablet (sustained release) 375 mg (as monohydrate) (<i>APO-Cefaclor CD</i>)
Cefazolin	Powder for injection 2 g (as sodium) (<i>Cefazolin-AFT</i>)
Cefepime	Powder for injection 1 g (as hydrochloride) (<i>Cefepime-AFT</i>)
Ceftriaxone	Powder for injection 1 g (as sodium) (<i>Ceftriaxone-AFT</i>)

	Powder for injection 2 g (as sodium) (<i>Ceftriaxone-AFT</i>)
Cyproterone	Tablet containing cyproterone acetate 50 mg (<i>APO-Cyproterone; GenRx Cyproterone Acetate</i>)
	Tablet containing cyproterone acetate 100 mg (<i>APO-Cyproterone; GenRx Cyproterone Acetate</i>)
Dabigatran etexilate	Capsule 75 mg (as mesilate) (<i>PHARMACOR DABIGATRAN</i>)
	Capsule 110 mg (as mesilate) (<i>PHARMACOR DABIGATRAN</i>)
	Capsule 150 mg (as mesilate) (<i>PHARMACOR DABIGATRAN</i>)
Doxycycline	Tablet 50 mg (as monohydrate) (<i>APO-Doxycycline</i>)
	Tablet 100 mg (as monohydrate) (<i>APO-Doxycycline</i>)
Esomeprazole	Tablet (enteric coated) 20 mg (as magnesium trihydrate) (<i>Esomeprazole Apotex</i>)
	Tablet (enteric coated) 40 mg (as magnesium trihydrate) (<i>Esomeprazole Apotex</i>)
Flucloxacillin	Capsule 250 mg (as sodium monohydrate) (<i>APO-Flucloxacillin</i>)
	Capsule 500 mg (as sodium monohydrate) (<i>APO-Flucloxacillin</i>)
Furosemide	Tablet 20 mg (<i>Urex-M</i>)
	Tablet 40 mg (<i>Urex</i>)
Gabapentin	Capsule 100 mg (<i>Gabapentin APOTEX</i>)
	Capsule 300 mg (<i>Gabapentin APOTEX</i>)
	Capsule 400 mg (<i>Gabapentin APOTEX</i>)
Glimepiride	Tablet 3 mg (<i>Amaryl</i>)
Hydromorphone	Oral solution containing hydromorphone hydrochloride 1 mg per mL, 1 mL (<i>Hydromorphone hydrochloride oral solution, USP (Medsurge)</i>)
Ipratropium	Nebuliser solution containing ipratropium bromide 250 micrograms (as monohydrate) in 1 mL single dose units, 30 (<i>APO-Ipratropium</i>)
	Nebuliser solution containing ipratropium bromide 500 micrograms (as monohydrate) in 1 mL single dose units, 30 (<i>APO-Ipratropium</i>)
Lamotrigine	Tablet 25 mg (<i>APO-Lamotrigine</i>)
	Tablet 50 mg (<i>APO-Lamotrigine</i>)
	Tablet 100 mg (<i>APO-Lamotrigine</i>)
	Tablet 200 mg (<i>APO-Lamotrigine</i>)
Levonorgestrel with ethinylestradiol	Pack containing 21 tablets 150 micrograms-30 micrograms and 7 inert tablets (<i>Monofeme 28</i>)

Metformin	Tablet (extended release) containing metformin hydrochloride 500 mg (<i>Metformin XR 500 APOTEX</i>)
	Tablet containing metformin hydrochloride 500 mg (<i>APO-Metformin 500</i>)
	Tablet containing metformin hydrochloride 850 mg (<i>APO-Metformin 850</i>)
	Tablet containing metformin hydrochloride 1 g (<i>APO-Metformin 1000</i>)
Mirtazapine	Tablet 15 mg (<i>APO-Mirtazapine</i>)
	Tablet 30 mg (<i>APO-Mirtazapine</i>)
	Tablet 45 mg (<i>APO-Mirtazapine</i>)
Moclobemide	Tablet 150 mg (<i>APO-Moclobemide</i>)
	Tablet 300 mg (<i>APO-Moclobemide</i>)
Olanzapine	Tablet 5 mg (orally disintegrating) (<i>Olanzapine ODT generichealth 5</i>)
Ondansetron	Tablet (orally disintegrating) 4 mg (<i>APO-Ondansetron ODT</i>)
	Tablet 4 mg (as hydrochloride dihydrate) (<i>Ondansetron APOTEX</i>)
	Tablet (orally disintegrating) 8 mg (<i>APO-Ondansetron ODT</i>)
	Tablet 8 mg (as hydrochloride dihydrate) (<i>Ondansetron APOTEX</i>)
Pravastatin	Tablet containing pravastatin sodium 10 mg (<i>APO-Pravastatin</i>)
	Tablet containing pravastatin sodium 20 mg (<i>APO-Pravastatin</i>)
	Tablet containing pravastatin sodium 40 mg (<i>APO-Pravastatin</i>)
	Tablet containing pravastatin sodium 80 mg (<i>APO-Pravastatin</i>)
Pregabalin	Capsule 25 mg (<i>LYPRALIN</i>)
	Capsule 75 mg (<i>LYPRALIN</i>)
	Capsule 150 mg (<i>LYPRALIN</i>)
	Capsule 300 mg (<i>LYPRALIN</i>)
Raloxifene	Tablet containing raloxifene hydrochloride 60 mg (<i>APO-Raloxifene</i>)
Sotalol	Tablet containing sotalol hydrochloride 80 mg (<i>APO-Sotalol</i>)
	Tablet containing sotalol hydrochloride 160 mg (<i>APO-Sotalol</i>)
Temozolomide	Capsule 180 mg (<i>Temodal</i>)
	Capsule 250 mg (<i>Temodal</i>)
Ziprasidone	Capsule 20 mg (as hydrochloride) (<i>APO-Ziprasidone</i>)

Capsule 40 mg (as hydrochloride) (*APO-Ziprasidone*)

Capsule 60 mg (as hydrochloride) (*APO-Ziprasidone*)

Capsule 80 mg (as hydrochloride) (*APO-Ziprasidone*)

Alteration of Manufacturer Code

Listed Drug	Form	Brand Name	Manufacturer Code	
Ferric derisomaltose	Injection 500 mg (iron) in 5 mL	<i>Monofer</i>	From: PF	To: FK
	Injection 1000 mg (iron) in 10 mL	<i>Monofer</i>	From: PF	To: FK

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Acalabrutinib	Pembrolizumab
Ibrutinib	Ustekinumab
Obinutuzumab	Venetoclax
Olaparib	Zanubrutinib

Supply Only – Additions

Listed Drug	Form
Hydralazine	Tablet containing hydralazine hydrochloride 25 mg
	Tablet containing hydralazine hydrochloride 50 mg
Triglycerides, medium chain	Oral liquid 225 mL, 15 (K.Quik)
Triglycerides - medium chain, formula	Sachets containing oral powder 16 g, 30 (MCT Pro-Cal)
Varenicline	Tablet 1 mg (as tartrate) (s19A)

Supply Only – Deletion

Listed Drug	Form
Essential amino acids formula with vitamins and minerals	Sachets containing oral powder 12.5 g, 50 (EAA Supplement)

Documents Incorporated by Reference

Listed Drug	Document incorporated	Document access
Acalabrutinib	Approved Product Information/Australian	TGA-approved Product Information is

Obinutuzumab	<p>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>available for download for free from the TGA website: https://www.tga.gov.au/product-information-0</p>
Olaparib	<p>Gynaecologic Cancer InterGroup (GCIG) guidelines/GCIG CA-125 response criteria. 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>The GCIG guidelines/GCIG CA-125 response criteria are a set of criteria for defining response and progression of ovarian cancer.</p>	<p>The GCIG guidelines/GCIG CA-125 response criteria are available for download for free in references from the Oxford University Press website https://academic.oup.com/jnci/article/96/6/487/2606756</p>
Acalabrutinib Ibrutinib Venetoclax Zanubrutinib	<p>International workshop on chronic lymphocytic leukemia (iwCLL) guidance. This document provides health professionals with guidance on various aspects of management of CLL/SLL. Notably, two of these are:</p> <p>(1) when to treat versus when to monitor the patient without therapy – see ‘Indications for treatment’ section; and</p> <p>(2) recognising progressive disease – see ‘Definition of response, relapse, and refractory disease’ section.</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>Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. <i>Blood</i> vol. 131, 25 (2018): 2745-2760.</p>
Olaparib	<p>The Response Evaluation Criteria in Solid Tumours (RECIST) guidelines. 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>The RECIST guidelines are a tool used widely for defining when tumours in cancer patients respond, stabilise and/or progress during treatment.</p>	<p>The RECIST guidelines are available for download for free from the RECIST Working Group website: https://recist.eortc.org/</p>
Pembrolizumab	<p>World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.</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>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 themselves, daily activity, and physical ability (walking, working, etc.).</p>	<p>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</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. 13) **(PB 128 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. 13)* (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 forms and brands of existing listed drugs, and ensuring the deletion of forms 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 5 new forms of existing drugs, and the addition of 19 new brands across 19 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 2024, these amounts are \$31.60 for general patients and \$7.70 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 essential amino acids formula with vitamins and minerals in the form sachets containing oral powder 12.5 g, 50 (EAA Supplement) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that the sponsor indicated the manufacture of this product will be discontinued and will no longer be available in Australia. The PBAC noted that the sponsor indicated there would be no interruption in supply, as the listing of a similar new product that was recommended at the November 2021 PBAC meeting would overlap with the delisting of this 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 1 month, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug hydralazine (Alphapress 25, Alphapress 50) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the importance of hydralazine in the management of hypertension, especially in urgent situations and in renal disease, and advised the delisting of these products may result in an unmet clinical need. The Department sought to retain these products in line with this advice, however the sponsor indicated retention was not viable due to financial reasons and wished to proceed with the delisting. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug triglycerides, medium chain in the form oral liquid 225 mL, 15 (K.Quik) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and that there are no suitable alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain this product in line with this advice, however the sponsor indicated retention is not viable due to financial reasons and wished to proceed with the delisting. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug triglycerides - medium chain, formula in the form sachets containing oral powder 16 g, 30 (MCT Pro-Cal) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and that there are no suitable alternatives on the PBS. The PBAC advised the delisting of this product may result in an unmet clinical need. The Department sought to retain this product in line with this advice, however the sponsor indicated retention is not viable due to financial reasons and wished to proceed with the delisting. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre-existing valid prescription to access this item pending transition to an alternative treatment option.

The drug varenicline in the form tablet 1 mg (as tartrate) (s19A) (APO-Varenicline (Canada)) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the Therapeutic Goods Act 1989 to address the shortage of varenicline in the form Tablet 1 mg (as tartrate). The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods lapsed on 30 November 2023. Patient access has not been affected by this delisting, as the approved form of the drug is now available and remains PBS-subsidised and accessible for patients. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 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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