EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 9)

PB 86 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 drug patiromer and the addition of forms of the listed drugs amino acid synthetic formula supplemented with long chain polyunsaturated fatty acids and medium chain triglycerides, azacitidine, glucagon, and naloxone. It also provides for the deletion of the listed drug saquinavir, the deletion of a form of the listed drug apomorphine, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs acalabrutinib, azacitidine, escitalopram, ibrutinib, idelalisib, obinutuzumab, pembrolizumab, tofacitinib, venetoclax, and zanubrutinib.

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

- the addition of 20 brands of existing pharmaceutical items
- the deletion of 16 brands of existing pharmaceutical items
- the deletion of a maximum quantity and number of repeats for an existing pharmaceutical item
- the addition of an authorised prescriber for an existing pharmaceutical item
- the alteration of a manufacturer code for existing pharmaceutical items
- the deletion of a responsible person to the list of responsible persons
- the deletion of 8 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 immediately after the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 8),* which will commence on 1 September 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. 9)*

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 9)* and may also be cited as PB 86 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 immediately after the commencement of the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 8)* (PB 79 of 2023), which will commence on 1 September 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 and deletion of forms of listed drugs, the addition and deletion of brands, the deletion of maximum quantities and numbers of repeats for brands of a pharmaceutical benefit, the addition of an authorised prescriber for a listed drug, the alteration of a manufacturer code for listed drugs, the deletion of a responsible person from 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

Patiromer

Drug Deleted

Listed Drug

Saquinavir

Forms Added

Listed Drug	***Form***
Amino acid synthetic formula supplemented with long chain	Oral powder with 2'-fucosyllactose and lacto-N-neotetraose, 400 g (Alfamino)

polyunsaturated fatty acids and medium chain triglycerides	
Azacitidine	Tablet 200 mg
	Tablet 300 mg
Glucagon	Injection set containing glucagon hydrochloride 1 mg (1 I.U.) and 1 mL solvent in disposable syringe (s19A)
Naloxone	Nasal spray 1.8 mg (as hydrochloride dihydrate) in 0.1 mL single dose unit, 2 (s19A)

Form Deleted

Listed Drug	***Form***
Apomorphine	Injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL

Brands Added

Listed Drug	***Form and Brand***
Amoxicillin with clavulanic acid	Tablet containing 500 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(Alphaclav Duo Viatris)*
	Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(Alphaclav Duo Forte Viatris)*
Bendamustine	Powder for injection containing bendamustine hydrochloride 25 mg *(Bendamustine Juno)*
	Powder for injection containing bendamustine hydrochloride 100 mg *(Bendamustine Juno)*
Clonidine	Tablet containing clonidine hydrochloride 100 micrograms *(Clonidine Lupin)*
Fingolimod	Capsule 500 micrograms (as hydrochloride) *(Fingolimod Sandoz)*
Levothyroxine	Tablet containing 50 micrograms anhydrous levothyroxine sodium *(APO-Levothyroxine; Levothyroxine Lup)*
	Tablet containing 75 micrograms anhydrous levothyroxine sodium *(APO-Levothyroxine; Levothyroxine Lup)*
	Tablet containing 100 micrograms anhydrous levothyroxine sodium *(APO-Levothyroxine; Levothyroxine Lup)*
	Tablet containing 200 micrograms anhydrous levothyroxine sodium *(APO-Levothyroxine; Levothyroxine Lup)*
Oxazepam	Tablet 15 mg *(Alepam 15)*
	Tablet 30 mg *(Alepam 30)*
Rosuvastatin	Tablet 5 mg (as calcium) *(Blooms Rosuvastatin)*

	Tablet 10 mg (as calcium) *(Blooms Rosuvastatin)*
	Tablet 20 mg (as calcium) *(Blooms Rosuvastatin)*
	Tablet 40 mg (as calcium) *(Blooms Rosuvastatin)*

Brands Deleted

Listed Drug	***Form and Brand***
Alendronic acid with colecalciferol	Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol *(FonatPlus)*
	Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol *(FonatPlus)*
Anastrozole	Tablet 1 mg *(Anastrozole FBM)*
Aripiprazole	Tablet 10 mg (*Aripiprazole generichealth)*
	Tablet 15 mg (*Aripiprazole generichealth)*
	Tablet 20 mg (*Aripiprazole generichealth)*
Entecavir	Tablet 1 mg (as monohydrate) *(Entecavir GH)*
Everolimus	Tablet 5 mg *(Everolimus Sandoz)*
	Tablet 10 mg *(Everolimus Sandoz)*
Imatinib	Capsule 100 mg (as mesilate) *(Imatinib GH)*
Letrozole	Tablet 2.5 mg *(Letrozole FBM)*
Levothyroxine	Tablet containing 125 micrograms anhydrous levothyroxine sodium *(Levothox)*
Methotrexate	Injection 50 mg in 2 mL vial *(Methotrexate Accord)*
Ondansetron	Tablet (orally disintegrating) 4 mg *(Ondansetron ODT Lupin)*
	Tablet (orally disintegrating) 8 mg *(Ondansetron ODT Lupin)*
Trastuzumab	Powder for I.V. infusion 150 mg *(Ontruzant)*

Deletion of Maximum Quantity and Number of Repeats

Listed Drug	***Form***	***Brand Name***	***Maximum Quantity***	***Number of Repeats***
Ondansetron	Wafer 4 mg	*Zofran Zydis*	4	0

Addition of Authorised Prescriber

Listed Drug	***Form***	***Brand Name***	***Authorised Prescriber***
Mifepristone and misoprostol	Pack containing 1 tablet mifepristone 200 mg and 4 tablets misoprostol 200 micrograms	*MS-2 Step*	From: **MP, NP** To: **MP, NP, MW**

Alteration of Manufacturer Code

Listed Drug	*Form*	*Brand Name*	*Manufacturer Code*
Chlorpromazine	Injection containing chlorpromazine hydrochloride 50 mg in 2 mL	*Largactil*	***From:*** SW ***To:*** *IX*
	Oral solution containing chlorpromazine hydrochloride 25 mg per 5 mL, 100 mL	*Largactil*	***From:*** SW ***To:*** *IX*
	Tablet containing chlorpromazine hydrochloride 25 mg	*Largactil*	***From:*** SW ***To:*** *IX*
	Tablet containing chlorpromazine hydrochloride 100 mg	*Largactil*	***From:*** SW ***To:*** *IX*
Periciazine	Tablet 2.5 mg	*Neulactil*	***From:*** SW ***To:*** *IX*
	Tablet 10 mg	*Neulactil*	***From:*** SW ***To:*** *IX*

Deletion of Responsible Person

For Benefit Medicines Pty Ltd *(FO)*

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug	
Acalabrutinib	Obinutuzumab
Azacitidine	Pembrolizumab
Escitalopram	Tofacitinib
Ibrutinib	Venetoclax
Idelalisib	Zanubrutinib

Supply Only – Deletions

Listed Drug	*Form and Brand*
Chlorpromazine	Tablet containing chlorpromazine hydrochloride 10 mg *(Largactil)*
Losartan	Tablet containing losartan potassium 25 mg *(Cozavan)*
	Tablet containing losartan potassium 50 mg *(Cozavan)*
Norethisterone with mestranol	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets *(Norinyl-1/28)*
Piroxicam	Dispersible tablet 10 mg *(Mobilis D-10)*
Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28 *(Systane)*
Polyvinyl alcohol	Eye drops 14 mg per mL, 15 mL *(Liquifilm Tears; PVA Tears)*
Propranolol	Tablet containing propranolol hydrochloride 160 mg *(Deralin 160)*

Documents Incorporated by Reference

Listed Drug	*Document incorporated*	*Document access*
Azacitidine Tofacitinib	**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
Tofacitinib	**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
Acalabrutinib Ibrutinib Idelalisib Obinutuzumab Venetoclax Zanubrutinib	**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: (1) when to treat versus when to monitor the patient without therapy – see 'Indications for treatment' section; and (2) recognising progressive disease – see 'Definition of response, relapse, and refractory disease' section. 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*.	Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. Blood vol. 131, 25 (2018): 2745-2760.
Pembrolizumab	**World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status 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 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

Diagnostic tools referenced in the Instrument

The following standard medical diagnostic tools are referenced in the Instrument but are not intended to incorporate a document by reference.

Listed Drug	*Diagnostic tool*	*Purpose and use in the Instrument*	*Reason this reference does not serve to incorporate a document*
Tofacitinib	**Bath Ankylosing Spondylitis Metrology Index (BASMI)**	The BASMI is a set of 10 questions designed to determine the degree of functional limitation in patients with Ankylosing Spondylitis (AS). BASMI is used to determine the severity of ankylosing spondylitis prior to initiation with a particular biological medicine for this condition.	BASMI is a diagnostic tool rather than a document incorporated. Reference: Jenkinson TR, Mallorie PA, Whitelock HC, Kennedy LG, Garrett SL, Calin A. Defining spinal mobility in ankylosing spondylitis (AS). The Bath AS Metrology Index. J Rheumatol. 1994 Sep;21(9):1694-8. PMID: 7799351
Pembrolizumab	**Combined Positive Score (CPS)**	The CPS is a scoring method that evaluates the number of PD - L1–staining cells (tumor cells, lymphocytes, macrophages) relative to all viable tumor cells. It predicts the response to pembrolizumab in patients with certain cancer types.	The CPS is the result of the following calculation and therefore does not serve as document in itself: The number of PD - L1–stained cells (tumour cells, lymphocytes, macrophages) divided by the number of all viable tumour cells (i.e. the total number of: PD - L1–positive tumour cells plus PD - L1–negative tumour cells). Although the result of the CPS calculation can exceed 100, the maximum score is defined as CPS 100. A minimum of 100 viable tumor cells in the PD - L1–stained slide is required for the specimen to be considered adequate for PD - L1 evaluation.

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. 9)

(PB 86 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. 9)* (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 listed drugs, 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 a new drug, the addition of five new forms of existing drugs, and the addition of 20 new brands across 16 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 apomorphine in the form injection containing apomorphine hydrochloride hemihydrate 20 mg in 2 mL (Movapo) was requested to be delisted from the PBS by the sponsor. The PBAC noted there are other strengths of apomorphine available on the PBS as well as several clinical alternatives and advised the delisting of this product would not result in an unmet clinical need.

The drug chlorpromazine in the form tablet containing chlorpromazine hydrochloride 10 mg (Largactil) was requested to be delisted from the PBS by the sponsor. The PBAC noted there are other strengths of chlorpromazine available on the PBS as well as several clinical alternatives and advised the delisting of this product 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 losartan in the forms tablet containing losartan potassium 25 mg (Cozavan), and tablet containing losartan potassium 50 mg (Cozavan) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are several alternatives on the PBS. The PBAC advised the delisting of these products would not result in an unmet clinical need. 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 this item pending transition to an alternative treatment option.

The drug norethisterone with mestranol in the form pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets (Norinyl-1/28) was requested to be delisted from the PBS by the sponsor. The PBAC noted the product was being discontinued by the sponsor and that there were 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 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 piroxicam in the form dispersible tablet 10 mg (Mobilis D-10) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that a higher strength form remains listed on the PBS. The PBAC advised that the delisting of this product 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 polyethylene glycol 400 with propylene glycol in the form eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 28 (Systane) was requested to be delisted from the PBS by the sponsor. The PBAC noted that the sponsor listed a new pack size of 30-units on 1 September 2022 and advised the delisting of this product 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 polyvinyl alcohol in the form eye drops 14 mg per mL, 15 mL (Liquifilm Tears; PVA Tears) was requested to be delisted from the PBS by the sponsor. The PBAC noted the availability of multiple alternatives on the PBS and advised the delisting of this product would not result in an unmet clinical need. 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 this item pending transition to an alternative treatment option.

The drug propranolol in the form tablet containing propranolol hydrochloride 160 mg (Deralin 160) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services and the availability of multiple alternatives on the PBS, including the 10 mg and 40 mg tablet forms of propranolol. The PBAC advised the delisting of this product 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 saquinavir in the form tablet 500 mg (as mesilate) (Invirase) was requested to be delisted from the PBS by the sponsor. The PBAC noted the low number of services in the last financial year and that there are multiple alternatives available on the PBS. The PBAC noted the sponsor intends to discontinue supply of the product in Australia. The PBAC advised the delisting of this drug would not result in an unmet clinical need.

Conclusion

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

Nikolai Tsyganov
Assistant Secretary
Pricing and PBS Policy Branch
Technology Assessment and Access Division
Department of Health and Aged Care