

EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2022 (No. 9)

PB 78 of 2022

Purpose

The purpose of this legislative instrument, made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* (the Act), is to amend the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) to make changes to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) and related matters.

PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (equivalent brands, responsible persons, prescribing circumstances, maximum quantities, number of repeats, determined quantity and pack quantity, section 100 only status and prescriber bag only status).

Authority

This Instrument exercises various powers in Part VII of the Act, as set out below:

Pharmaceutical benefits listed on the PBS

Subsection 85(2) provides that the Minister may declare drugs and medicinal preparations to which Part VII applies. A drug or medicinal preparation for which there is a declaration in force under subsection 85(2) is a 'listed drug' (subsection 84(1)). Subsections 85(3) and 85(5) respectively provide that the Minister may determine the form or forms of a listed drug and the manner of administration of a form of a listed drug. A listed drug in a determined form with a determined manner of administration for that form is a pharmaceutical item (section 84AB). Subsection 85(6) provides that the Minister may determine a brand of a pharmaceutical item.

The Minister may also determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1)). Under the provisions of section 84AK the Minister may determine the determined quantity and pack quantity for a brand of a pharmaceutical item.

Prescribing pharmaceutical benefits

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(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 of the listed drugs gilteritinib, niraparib, and selinexor and forms of the listed drugs cabazitaxel, glatiramer, oxybutynin, polyethylene glycol 400 with propylene glycol, and triglycerides, medium chain to the Schedule of Pharmaceutical Benefits. It also provides for the deletion of the listed drug eptifibatid and for the alteration of circumstances in which a prescription may be written for the supply of the listed drugs alirocumab, apremilast, brentuximab vedotin, cabazitaxel, ciclosporin, crizotinib, dapagliflozin, entrectinib, imatinib, molnupiravir, nirmatrelvir and ritonavir, olaparib, pembrolizumab, rituximab, ruxolitinib, sonidegib, sunitinib, vedolizumab, vismodegib and vorinostat.

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

- the addition of 8 brands of existing pharmaceutical items;
- the deletion of 2 brands of existing pharmaceutical items;
- the deletion of a pack quantity for 1 existing pharmaceutical item;
- the alteration of responsible persons code for 8 existing brands of pharmaceutical items;
- the addition of 1 responsible person to the list of responsible persons;
- the deletion of 1 responsible person from the list of responsible persons;
- the addition of 7 existing pharmaceutical items covered under supply only arrangements; and

- the deletion of 1 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 September 2022.

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 2022 (No. 9)

Section 1 Name of Instrument

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 9)* and may also be cited as PB 78 of 2022.

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 September 2022.

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 forms of listed drugs, the addition and deletion of brands, the deletion of a pack quantity, the alteration of responsible person code for brands of pharmaceutical benefits, the addition and deletion of responsible persons from the list of responsible persons, the addition and 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**

Listed Drugs Added

Listed Drug

Gilteritinib

Niraparib

Selinexor

Listed Drug Deleted

Listed Drug

Eptifibatide

Forms Added

Listed Drug

Form

Cabazitaxel

Solution concentrate for I.V. infusion 60 mg in 3 mL

Glatiramer

Injection containing glatiramer acetate 40 mg in 1 mL single dose pre-filled pen

Oxybutynin	Tablet containing oxybutynin chloride 5 mg (s19A)
Polyethylene glycol 400 with propylene glycol	Eye drops 4 mg-3 mg per mL, single dose units 0.8 mL, 30
Triglycerides, medium chain	Oral liquid 225 mL, 15 (K.Quik)

Brands Added

<i>Listed Drug</i>	<i>Form and Brand</i>
Bortezomib	Powder for injection 3.5 mg (<i>Bortezomib-AFT</i>)
Cefazolin	Powder for injection 2 g (as sodium) (<i>Cefazolin-AFT</i>)
Icatibant	Injection 30 mg (as acetate) in 3 mL single use pre-filled syringe (<i>Fyzant</i>)
Pemetrexed	Powder for I.V. infusion 100 mg (as disodium) (<i>Pemetrexed-AFT</i>) Powder for I.V. infusion 500 mg (as disodium) (<i>Pemetrexed-AFT</i>)
Sunitinib	Capsule 25 mg (<i>ARX-Sunitinib</i>) Capsule 37.5 mg (<i>ARX-Sunitinib</i>) Capsule 50 mg (<i>ARX-Sunitinib</i>)

Brands Deleted

<i>Listed Drug</i>	<i>Form and Brand</i>
Glimepiride	Tablet 2 mg (<i>Dimirel</i>)
Leflunomide	Tablet 20 mg (<i>Arablox</i>)

Deletion of Pack Quantity

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Pack Quantity</i>
Venetoclax	Tablet 10 mg	Venclexta	14

Alteration of Responsible Person Code

<i>Listed Drug</i>	<i>Form</i>	<i>Brand Name</i>	<i>Responsible Person</i>	
Adalimumab	Injection 20 mg in 0.4 mL pre-filled syringe	<i>Amgevita</i>	From: TX	To: XT
	Injection 40 mg in 0.8 mL pre-filled pen	<i>Amgevita</i>	From: TX	To: XT
	Injection 40 mg in 0.8 mL pre-filled syringe	<i>Amgevita</i>	From: TX	To: XT
Gliclazide	Tablet 60 mg (modified release)	<i>ARDIX GLICLAZIDE 60mg MR</i>	From: RX	To: XT
Hydroxycarbamide	Capsule 500 mg	<i>Hydrea</i>	From: BQ	To: LM

Siltuximab	Powder for injection 100 mg	<i>Sylvant</i>	From: EY	To: RJ
	Powder for injection 400 mg	<i>Sylvant</i>	From: EY	To: RJ
Valganciclovir	Powder for oral solution 50 mg (as hydrochloride) per mL, 100 mL	<i>Valcyte</i>	From: RO	To: PB

Addition of Responsible Person Code

ANTENGENE (AUS) PTY. LTD. (TG)

Deletion of Responsible Person Code

EUSA Pharma (Australia) Pty Ltd (EY)

Alteration of Circumstances in Which a Prescription May be Written

Listed Drug

Alirocumab	Nirmatrelvir and ritonavir
Apremilast	Olaparib
Brentuximab vedotin	Pembrolizumab
Cabazitaxel	Rituximab
Ciclosporin	Ruxolitinib
Crizotinib	Sonidegib
Dapagliflozin	Sunitinib
Entrectinib	Vedolizumab
Imatinib	Vismodegib
Molnupiravir	Vorinostat

Supply Only – Additions

Note: Supply Only benefits are available on the Schedule for dispensing only, for a period of up to 12 months.

Listed Drug	Form and Brand
Norethisterone with mestranol	Pack containing 21 tablets 1 mg-50 micrograms and 7 inert tablets (<i>Norinyl-1/28</i>)
Rituximab	Solution for I.V. infusion 100 mg in 10 mL (<i>Ruxience, Riximyo, Truxima</i>)
	Solution for I.V. infusion 500 mg in 50 mL (<i>Ruxience, Riximyo, Truxima</i>)

Supply Only – Deletions

Listed Drug	Form and Brand
Rivaroxaban	Tablet 10 mg (<i>Xarelto</i>)

Documents Incorporated by Reference

<i>Listed Drug</i>	<i>Document incorporated</i>	<i>Document access</i>
Ruxolitinib	<p>Age-Adjusted Dynamic International Prognostic Scoring System (DIPSS). 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 Age-Adjusted DIPSS is a medical diagnostic tool used to help assess the severity of myelofibrosis for younger patients (under 65 years old) by taking into account progression of disease over time and can be used to evaluate prognosis as a patient's condition evolves.</p>	<p>The age-adjusted DIPSS is available for download for free from the Blood Journal website: https://ashpublications.org/blood/article/115/9/1703/27216/A-dynamic-prognostic-model-to-predict-survival-in</p> <p>Blood (2010) 115 (9): 1703–1708</p>
Dupilumab Upadacitinib	<p>Dermatology Life Quality Index (DLQI). 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 DLQI is designed to measure the health-related quality of life of adult patients suffering from a skin disease.</p>	<p>The DLQI is available for download for free from the Cardiff University website: https://www.cardiff.ac.uk/medicine/resources/quality-of-life-questionnaires/dermatology-life-quality-index</p>
Ruxolitinib	<p>Dynamic International Prognostic Scoring System (DIPSS). 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 DIPSS is a medical diagnostic tool used to help assess the severity of myelofibrosis by taking into account progression of disease over time and can be used to evaluate prognosis as a patient's condition evolves.</p>	<p>The DIPSS is available for download for free from the Blood Journal website: https://ashpublications.org/blood/article/115/9/1703/27216/A-dynamic-prognostic-model-to-predict-survival-in</p> <p>Blood (2010) 115 (9): 1703–1708</p>
Dupilumab Upadacitinib	<p>Eczema Area and Severity Index (EASI). The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The EASI is a validated scoring system that grades the physical signs of atopic dermatitis/eczema.</p>	<p>Instructions on the use of the Eczema Area and Severity Index and copyright details are available for download for free from the Dupixent (UK) website: https://www.dupixent.co.uk/-/media/EMS/Conditions/Dermatology/Brands/Dupixent-UK/global/1051-EASI-Leaflet-v6-webready.pdf</p>
Niraparib 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>
Ruxolitinib	<p>International Prognostic Scoring System (IPSS). The document is incorporated as in force</p>	<p>The International Prognostic Scoring System (IPSS) is available</p>

	<p>on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The IPSS is a medical diagnostic tool used to help assess the severity of myelodysplastic syndrome, through the evaluation of the proportion of blast cells in a patient's bonemarrow, the type of chromosomal changes (if any) in the marrow cells, and the presence of one or more low blood cell counts (cytopenias).</p>	<p>for download for free from the Blood Journal website: https://ashpublications.org/blood Blood (1997) 89 (6): 2079–2088.</p>
Molnupiravir Nirmatrelvir and ritonavir	<p>Modified Monash Model (MMM). 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 MMM is used to define whether a location where a person lives is a city, rural, remote or very remote.</p>	<p>The MMM is available for download for free from the Department of Health website: https://www.health.gov.au/health-topics/rural-health-workforce/classifications/mmm</p>
Dupilumab Upadacitinib	<p>Physicians Global Assessment (PGA) (5-point scale). The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <i>Legislation Act 2003</i>.</p> <p>The PGA is a 5-point scale that measures the severity of atopic dermatitis.</p>	<p>The Physician's Global Assessment is not publicly available, but can be obtained free of charge from Sanofi Medical Information, along with instructions on the use of the Physician's Global Assessment (5-point scale) by phoning 1800 818 806 or email MedInfo.Australia@sanofi.com</p>
Niraparib Olaparib	<p>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>
Imatinib	<p>Southwest Oncology Group standard criteria (SWOG). 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>Southwest Oncology Group standard criteria (SWOG) are standardised guidelines used for assessing a response to treatment of cancer in clinical trials.</p>	<p>Southwest Oncology Group standard criteria (SWOG) is available for download for free from the National Institute for Health and Care Excellence (NICE) webpage: https://www.nice.org.uk/guidance/ta86/chapter/appendix-d-southwest-oncology-group-swog-criteria-for-assessing-tumour-response</p>
Apremilast	<p>Therapeutic Goods Administration (TGA)-approved Product Information. The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the <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</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>

medicine.

Cabazitaxel
Crizotinib
Entrectinib
Gilteritinib
Sunitinib

World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status. The document is incorporated as in force on the day this Instrument takes effect, pursuant to paragraph 14(1)(b) of the *Legislation Act 2003*.

The WHO/ECOG performance status is a standard medical diagnostic tool used to measure how cancer impacts a patient's daily living abilities, by evaluating a patient's level of functioning in terms of their ability to care for themselves, daily activity, and physical ability (walking, working, etc.).

The WHO/ECOG Performance Status is available for download for free from the ECOG-ACRIN Cancer Research Group website: <https://ecog-acrin.org/resources/ecog-performance-status>

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2022 (No. 9) **(PB 78 of 2022)**

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 2022 (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 on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

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 PBS medicines. The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to

medicines on the PBS are evidence-based. The Instrument includes the addition of three new drugs, five new forms across five existing drugs and the addition of eight new brands across eight 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 2022, these fees are up to \$42.50 for general patients and up to \$6.80 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 eptifibatide (Integrilin[®]) was requested to be delisted from the PBS by the sponsor. The PBAC noted the products were being discontinued by the sponsor and that there were available clinical alternatives. 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.

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