**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 11)***

**PB 105 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 trastuzumab deruxtecan and the addition of forms of the listed drugs amoxicillin with clavulanic acid, enoxaparin, glycomacropeptide and essential amino acids with vitamins and minerals, and methylprednisolone. It also provides for the deletion of a form of the listed drug glycomacropeptide and essential amino acids with vitamins and minerals and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abatacept, adalimumab, baricitinib, blinatumomab, budesonide, certolizumab pegol, empagliflozin, etanercept, fremanezumab, golimumab, infliximab, somatropin, tocilizumab, tofacitinib, upadacitinib, and ustekinumab.

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

- the addition of 27 brands of existing pharmaceutical items
- the deletion of 9 brands of existing pharmaceutical items
- the alteration of brand name for 12 existing pharmaceutical items
- the addition of a maximum quantity and number of repeats for 8 existing pharmaceutical items
- the alteration of number of repeats for 5 brands of existing pharmaceutical items
- the alteration of manufacturer codes for 17 brands of existing pharmaceutical items
- the addition of 3 responsible persons to the list of responsible persons
- the deletion of a responsible person from the list of responsible persons

- the deletion of 43 pharmaceutical items covered under Supply Only arrangements.

These changes are summarised, by subject matter, in the Attachment.

**Consultation**

The involvement of interested parties through the membership of the PBAC constitutes a formal and ongoing process of consultation. The PBAC is an independent expert body established by section 100A of the Act which makes recommendations to the Minister about which drugs and medicinal preparations should be available to Australians as pharmaceutical benefits. The PBAC members are appointed following nomination by prescribed organisations and associations from consumers, health economists, practising community pharmacists, general practitioners, clinical pharmacologists and specialists, with at least one member selected from each of those interests or professions. Remaining members are persons whom the Minister is satisfied have qualifications and experience in a field relevant to the functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. In addition, an industry nominee has been appointed to the PBAC membership under the PBS Access and Sustainability Package of reforms announced in May 2015. When recommending the listing of a medicine on the PBS, PBAC takes into account the medical conditions for which the medicine has been approved for use in Australia, its clinical effectiveness, safety and cost-effectiveness compared with other treatments.

Pharmaceutical companies are consulted throughout the process of the listing of their medicines on the PBS and in relation to changes to those listings. This includes the company submission to the PBAC and involvement throughout the PBAC process, negotiations or consultation on price, guarantee of supply and agreement to final listing details.

It was considered that further consultation for this Instrument was unnecessary due to the nature of the consultation that had already taken place.

**General**

A provision-by-provision description of this Instrument is contained in the Attachment.

This Instrument commences on 1 November 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. 11)***

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 11)* and may also be cited as PB 105 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 November 2023.

**Section 3 Authority**

This section specifies that sections 84AF, 84AK, 85, 85A, 88 and 101 of the *National Health Act 1953* provide the authority for the making of this Instrument.

**Section 4 Schedules**

Section 4 provides that each instrument that is specified in a Schedule to the Instrument is amended or repealed as set out in the applicable items in the Schedule concerned, and any other item in a Schedule to the Instrument has effect according to its terms.

**Schedule 1 Amendments**

The amendments in Schedule 1 involve the addition of a listed drug, the addition and deletion of forms of listed drugs, the addition and deletion of brands, the alteration of brand name for brands of pharmaceutical items, the addition of maximum quantities and numbers of repeats for brands of pharmaceutical benefits, the alteration of number of repeats for brands of pharmaceutical items, the alteration of manufacturer codes for brands of pharmaceutical items, the addition and deletion of responsible persons 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***

Trastuzumab deruxtecan

## Forms Added

| *Listed Drug* | *Form* |
|---|---|
| Amoxicillin with clavulanic acid | Powder for oral suspension containing 400 mg amoxicillin (as trihydrate) with 57 mg clavulanic acid (as potassium clavulanate) per 5 mL, 50 mL (S19A) |
| Enoxaparin | Injection containing enoxaparin sodium 120 mg (12,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe |
| | Injection containing enoxaparin sodium 150 mg (15,000 I.U. anti-Xa) in 1 mL pre-filled syringe |
| Glycomacropeptide | Sachets containing oral powder 40 g, 30 (Camino Pro Bettermilk) |

| | |
|---|---|
| and essential amino acids with vitamins and minerals | |
| Methylprednisolone | Powder for injection 40 mg (as sodium succinate) (S19A) |

## Form Deleted

| *Listed Drug* | *Form* |
|---|---|
| Glycomacropeptide and essential amino acids with vitamins and minerals | Sachets containing oral powder 49 g, 30 (Camino Pro Bettermilk) |

## Brands Added

| *Listed Drug* | *Form and Brand* |
|---|---|
| Atorvastatin | Tablet 10 mg (as calcium) *(BTC Atorvastatin)* |
| | Tablet 20 mg (as calcium) *(BTC Atorvastatin)* |
| | Tablet 40 mg (as calcium) *(BTC Atorvastatin)* |
| | Tablet 80 mg (as calcium) *(BTC Atorvastatin)* |
| Carbimazole | Tablet 5 mg *(THIRAZOL)* |
| Enoxaparin | Injection containing enoxaparin sodium 20 mg (2,000 I.U. anti-Xa) in 0.2 mL pre-filled syringe *(Exarane)* |
| | Injection containing enoxaparin sodium 40 mg (4,000 I.U. anti-Xa) in 0.4 mL pre-filled syringe *(Exarane)* |
| | Injection containing enoxaparin sodium 60 mg (6,000 I.U. anti-Xa) in 0.6 mL pre-filled syringe *(Exarane)* |
| | Injection containing enoxaparin sodium 80 mg (8,000 I.U. anti-Xa) in 0.8 mL pre-filled syringe *(Exarane)* |
| | Injection containing enoxaparin sodium 100 mg (10,000 I.U. anti-Xa) in 1 mL pre-filled syringe *(Exarane)* |
| Ezetimibe with simvastatin | Tablet 10 mg-10 mg *(Zimybe 10/10)* |
| | Tablet 10 mg-20 mg *(Zimybe 10/20)* |
| | Tablet 10 mg-40 mg *(Zimybe 10/40)* |
| | Tablet 10 mg-80 mg *(Zimybe 10/80)* |
| Fosaprepitant | Powder for I.V. infusion 150 mg *(FOSAPREPITANT MSN)* |
| Ibuprofen | Tablet 400 mg *(MEDICHOICE Ibuprofen 400 mg)* |
| Irinotecan | I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL |

| | |
|---|---|
| | *(IRINOTECAN BAXTER)* |
| Levothyroxine | Tablet containing 50 micrograms anhydrous levothyroxine sodium *(Levothyroxine Sandoz)* |
| | Tablet containing 75 micrograms anhydrous levothyroxine sodium *(Levothyroxine Sandoz)* |
| | Tablet containing 100 micrograms anhydrous levothyroxine sodium *(Levothyroxine Sandoz)* |
| | Tablet containing 200 micrograms anhydrous levothyroxine sodium *(Levothyroxine Sandoz)* |
| Methylprednisolone | Cream containing methylprednisolone aceponate 1 mg per g, 15 g *(Supriad Cream)* |
| | Fatty ointment containing methylprednisolone aceponate 1 mg per g, 15 g *(Supriad Fatty Ointment)* |
| | Ointment containing methylprednisolone aceponate 1 mg per g, 15 g *(Supriad Ointment)* |
| Naltrexone | Tablet containing naltrexone hydrochloride 50 mg *(ARX-NALTREXONE)* |
| Varenicline | Tablet 1 mg (as tartrate) *(PHARMACOR VARENICLINE)* |
| | Box containing 11 tablets 0.5 mg (as tartrate) and 14 tablets 1 mg (as tartrate) in the first pack and 28 tablets 1 mg (as tartrate) in the second pack *(PHARMACOR VARENICLINE)* |

**Brands Deleted**

| ***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)* |
| Bortezomib | Powder for injection 1 mg *(Bortezomib Juno)* |
| Carmellose | Eye drops containing carmellose sodium 5 mg per mL, single dose units 0.4 mL, 30 *(Optifresh Tears)* |
| | Eye drops containing carmellose sodium 10 mg per mL, single dose units 0.4 mL, 30 *(Optifresh Plus)* |
| Clopidogrel with aspirin | Tablet 75 mg (as hydrogen sulfate)-100 mg *(CLOPIDOGREL/ASPIRIN AN 75/100)* |
| Glimepiride | Tablet 4 mg *(Amaryl)* |
| Paracetamol | Tablet 665 mg (modified release) *(CHEMISTS' OWN OSTEO RELIEF PARACETAMOL)* |
| Pregabalin | Capsule 300 mg *(Pregabalin GH)* |
| Valganciclovir | Tablet 450 mg (as hydrochloride) *(Valganciclovir Mylan)* |

**Alteration of Brand Name**

| *Listed Drug* | *Form* | *Brand Name* | |
|---|---|---|---|
| Amlodipine with valsartan | Tablet 5 mg (as besilate)-80 mg | ***From:*** *Valsartan/Amlodipine Novartis 80/5* | ***To:*** *Amlodipine/Valsartan Novartis 5/80* |
| | Tablet 5 mg (as besilate)-160 mg | ***From:*** *Valsartan/Amlodipine Novartis 160/5* | ***To:*** *Amlodipine/Valsartan Novartis 5/160* |
| | Tablet 5 mg (as besilate)-320 mg | ***From:*** *Valsartan/Amlodipine Novartis 320/5* | ***To:*** *Amlodipine/Valsartan Novartis 5/320* |
| | Tablet 10 mg (as besilate)-160 mg | ***From:*** *Valsartan/Amlodipine Novartis 160/10* | ***To:*** *Amlodipine/Valsartan Novartis 10/160* |
| | Tablet 10 mg (as besilate)-320 mg | ***From:*** *Valsartan/Amlodipine Novartis 320/10* | ***To:*** *Amlodipine/Valsartan Novartis 10/320* |
| Amlodipine with valsartan and hydrochlorothiazide | Tablet 5 mg (as besilate)-160 mg-12.5 mg | ***From:*** *Valsartan/Amlodipine/HCT Novartis 160/5/12.5* | ***To:*** *Amlodipine/Valsartan/HCT Novartis 5/160/12.5* |
| | Tablet 5 mg (as besilate)-160 mg-25 mg | ***From:*** *Valsartan/Amlodipine/HCT Novartis 160/5/25* | ***To:*** *Amlodipine/Valsartan/HCT Novartis 5/160/25* |
| | Tablet 10 mg (as besilate)-160 mg-12.5 mg | ***From:*** *Valsartan/Amlodipine/HCT Novartis 160/10/12.5* | ***To:*** *Amlodipine/Valsartan/HCT Novartis 10/160/12.5* |
| | Tablet 10 mg (as besilate)-160 mg-25 mg | ***From:*** *Valsartan/Amlodipine/HCT Novartis 160/10/25* | ***To:*** *Amlodipine/Valsartan/HCT Novartis 10/160/25* |
| | Tablet 10 mg (as besilate)-320 mg-25 mg | ***From:*** *Valsartan/Amlodipine/HCT Novartis 320/10/25* | ***To:*** *Amlodipine/Valsartan/HCT Novartis 10/320/25* |
| Atropine | Injection containing atropine sulfate monohydrate 600 micrograms in 1 mL | ***From:*** *Pfizer Australia Pty Ltd* | ***To:*** *Atropine Injection (Pfizer)* |
| Lidocaine | Injection containing lidocaine hydrochloride monohydrate 50 mg in 5 mL | ***From:*** *Pfizer Australia Pty Ltd* | ***To:*** *Lignocaine Injection (Pfizer)* |

## Addition of Maximum Quantity and Number of Repeats

| *Listed Drug* | *Form* | *Brand Name* | *Maximum Quantity* | *Number of Repeats* |
|---|---|---|---|---|
| Budesonide | Tablet 500 micrograms (orally disintegrating) | *Jorveza* | 60 | 8 |
| | Tablet 1 mg (orally disintegrating) | *Jorveza* | 60 | 8 |
| Etanercept | Injection set containing 4 vials powder for injection 25 mg and 4 pre-filled syringes solvent 1 mL | *Enbrel* | 2 | 1 |
| | Injection 50 mg in 1 mL single use auto-injector, 4 | *Enbrel* | 1 | 1 |
| | Injections 50 mg in 1 mL single use pre-filled syringes, 4 | *Enbrel* | 1 | 1 |
| Infliximab | Powder for I.V. infusion 100 mg | *Inflectra* | 3 | 2 |
| | | *Remicade* | 3 | 2 |
| | | *Renflexis* | 3 | 2 |

## Alteration of Number of Repeats

| *Listed Drug* | *Form* | *Brand Name* | *Number of Repeats* |
|---|---|---|---|
| Ursodeoxycholic acid | Capsule 250 mg | *APO-Ursodeoxycholic acid* | ***From:*** 2 ***To:*** 4 |
| | | *Ursodox GH* | ***From:*** 2 ***To:*** 4 |
| | | *Ursofalk* | ***From:*** 2 ***To:*** 4 |
| | | *Ursosan* | ***From:*** 2 ***To:*** 4 |
| | Tablet 500 mg | *Ursofalk* | ***From:*** 2 ***To:*** 4 |

## Alteration of Manufacturer Code

| *Listed Drug* | *Form* | *Brand Name* | *Manufacturer Code* |
|---|---|---|---|
| Atropine | Injection containing atropine sulfate monohydrate 600 micrograms in 1 mL | *Atropine Injection (Pfizer)* | ***From:*** PF ***To:*** WZ |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | *Rilast TURBUHALER 200/6* | ***From:*** ZA ***To:*** XT |
| | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses | *Rilast TURBUHALER 400/12* | ***From:*** ZA ***To:*** XT |

| | | | | |
|---|---|---|---|---|
| | Pressurised inhalation containing budesonide 100 micrograms with formoterol fumarate dihydrate 3 micrograms per dose, 120 doses | *Rilast RAPIHALER 100/3* | ***From:*** ZA | ***To:*** XT |
| | Pressurised inhalation containing budesonide 200 micrograms with formoterol fumarate dihydrate 6 micrograms per dose, 120 doses | *Rilast RAPIHALER 200/6* | ***From:*** ZA | ***To:*** XT |
| Lidocaine | Injection containing lidocaine hydrochloride monohydrate 50 mg in 5 mL | *Lignocaine Injection (Pfizer)* | ***From:*** PF | ***To:*** WZ |
| Olanzapine | Powder for injection 210 mg (as pamoate monohydrate) with diluent | *Zyprexa Relprevv* | ***From:*** LY | ***To:*** PB |
| | Powder for injection 300 mg (as pamoate monohydrate) with diluent | *Zyprexa Relprevv* | ***From:*** LY | ***To:*** PB |
| | Powder for injection 405 mg (as pamoate monohydrate) with diluent | *Zyprexa Relprevv* | ***From:*** LY | ***To:*** PB |
| | Tablet 2.5 mg | *Zyprexa* | ***From:*** LY | ***To:*** PB |
| | Tablet 5 mg | *Zyprexa* | ***From:*** LY | ***To:*** PB |
| | Tablet 7.5 mg | *Zyprexa* | ***From:*** LY | ***To:*** PB |
| | Tablet 10 mg | *Zyprexa* | ***From:*** LY | ***To:*** PB |
| | Wafer 5 mg | *Zyprexa Zydis* | ***From:*** LY | ***To:*** PB |
| | Wafer 10 mg | *Zyprexa Zydis* | ***From:*** LY | ***To:*** PB |
| | Wafer 15 mg | *Zyprexa Zydis* | ***From:*** LY | ***To:*** PB |
| | Wafer 20 mg | *Zyprexa Zydis* | ***From:*** LY | ***To:*** PB |

**Addition of Responsible Persons**

Leo Pharma Pty Ltd *(LG)*

Nova Pharmaceuticals Australasia Pty Ltd *(NB)*

Bridgewest Perth Pharma Pty Ltd *(WZ)*

**Deletion of Responsible Person**

AstraZeneca Pty Ltd *(ZA)*

## Alteration of Circumstances in Which a Prescription May be Written

***Listed Drug***

| | |
|---|---|
| Abatacept | Fremanezumab |
| Adalimumab | Golimumab |
| Baricitinib | Infliximab |
| Blinatumomab | Somatropin |
| Budesonide | Tocilizumab |
| Certolizumab pegol | Tofacitinib |
| Empagliflozin | Upadacitinib |
| Etanercept | Ustekinumab |

## Supply Only – Deletions

| ***Listed Drug*** | ***Form and Brand*** |
|---|---|
| Donepezil | Tablet containing donepezil hydrochloride 5 mg *(APO-Donepezil; Arazil; Aricept; Aridon 5; Aridon APN 5; Donepezil GH; Donepezil Sandoz; NOUMED DONEPEZIL)* |
| | Tablet containing donepezil hydrochloride 10 mg *(APO-Donepezil; Arazil; Aricept; Aridon 10; Aridon APN 10; Donepezil GH; Donepezil Sandoz; NOUMED DONEPEZIL)* |
| Galantamine | Capsule (prolonged release) 8 mg (as hydrobromide) (*APO-Galantamine MR; Galantyl; Gamine XR; Reminyl)* |
| | Capsule (prolonged release) 16 mg (as hydrobromide) (*APO-Galantamine MR; Galantyl; Gamine XR; Reminyl)* |
| | Capsule (prolonged release) 24 mg (as hydrobromide) (*APO-Galantamine MR; Galantyl; Gamine XR; Reminyl)* |
| Gentamicin | Eye drops 3 mg (as sulfate) per mL, 5 mL *(Genoptic)* |
| Memantine | Tablet containing memantine hydrochloride 10 mg *(APO-Memantine; Ebixa; Memantine generichealth; Memanxa)* |
| | Tablet containing memantine hydrochloride 20 mg *(APO-Memantine; Ebixa; Memantine generichealth)* |
| Rivastigmine | Capsule 1.5 mg (as hydrogen tartrate) *(Exelon)* |
| | Capsule 3 mg (as hydrogen tartrate) *(Exelon)* |
| | Capsule 4.5 mg (as hydrogen tartrate) *(Exelon)* |
| | Capsule 6 mg (as hydrogen tartrate) *(Exelon)* |
| | Transdermal patch 9 mg *(Exelon Patch 5)* |

Transdermal patch 18 mg *(Exelon Patch 10)*

Transdermal patch 27 mg *(Exelon Patch 15)*

## Documents Incorporated by Reference

| *Listed Drug* | *Document incorporated* | *Document access* |
|---|---|---|
| Abatacept<br>Adalimumab<br>Baricitinib<br>Blinatumomab<br>Certolizumab Pegol<br>Etanercept<br>Golimumab<br>Tocilizumab<br>Tofacitinib<br>Upadacitinib<br>Ustekinumab | **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.*<br><br>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 |
| Empagliflozin | **New York Heart Association (NYHA) classification.** 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.<br><br>The NYHA classification system is used to define the degree of heart failure. | The NYHA classification system is available for download for free from the Heart Foundation website (contained within the heart failure clinical guidelines): https://www.heartfoundation.org.au/Conditions/Heart-failure-clinical-guidelines |
| Blinatumomab<br>Trastuzumab deruxtecan | **World Health Organization (WHO)/Eastern Cooperative Oncology Group (ECOG) Performance Status/Performance Status Score.**<br>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*.<br><br>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 |

# 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. 11)***

**(PB 105 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. 11)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

## Human rights implications

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

*The Right to Social Security*

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

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

*The Right to Health*

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

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

## Analysis

The Instrument advances the right to health and the right to social security by providing new drugs, and new forms and brands of existing listed drugs, and ensuring the deletion of listed drugs, 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 one new drug, the addition of five new forms of existing drugs, and the addition of 27 new brands across 27 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 gentamicin, in the form eye drops 3 mg (as sulfate) per mL, 5 mL (Genoptic), was requested to be delisted from the PBS by the sponsor. The PBAC reiterated the risk of antimicrobial resistance associated with reducing the range of antimicrobials on the PBS and advised the delisting of this product may result in an unmet clinical need. The Department sought to retain the product in line with this advice, however the sponsor indicated retention is unviable due to discontinuation of the product and wished to proceed with the delisting. This item was available on the 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 glycomacropeptide and essential amino acids with vitamins and minerals in the form sachets containing oral powder 49 g, 30 (Camino Pro Bettermilk) was requested to be delisted from the PBS by the sponsor. The PBAC noted that a new pack size with new formulation of Camino Pro Bettermilk was recommended for listing at the March 2023 PBAC meeting. The PBAC advised the delisting of this product would not result in an unmet clinical need should the alternative pack size be listed on the PBS.

**Conclusion**

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

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