**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 12)***

**PB 112 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 forms of the listed drugs adefovir, essential amino acids formula with vitamins and minerals, morphine and tofacitinib. It also provides for the deletion of forms of the listed drugs amoxicillin, colestyramine, fentanyl, ibandronic acid, pancrelipase, pyridostigmine and ranitidine, and the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs adalimumab, bimekizumab, certolizumab pegol, darolutamide, durvalumab, etanercept, golimumab, infliximab, ixekizumab, nivolumab, pembrolizumab, secukinumab, tofacitinib, upadacitinib and zoledronic acid.

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

* the addition of 37 brands of existing pharmaceutical items
* the deletion of 27 brands of existing pharmaceutical items
* the addition of a maximum quantity and number of repeats for 4 existing pharmaceutical items
* the deletion of a maximum quantity and number of repeats for 6 existing pharmaceutical items
* the deletion of a pack quantity for 5 existing pharmaceutical items
* the addition of a Responsible Person to the list of Responsible Persons
* the addition of 10 pharmaceutical items covered under Supply Only arrangements
* the deletion of a pharmaceutical item covered under Supply Only arrangements.

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

**Consultation**

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

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

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

**General**

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

This Instrument commences on 1 December 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. 12)***

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 12)* and may also be cited as PB 112 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 December 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**

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

**Schedule 1 Amendments**

The amendments in Schedule 1 involve the addition and deletion of forms of listed drugs, the addition and deletion of brands, the addition and deletion of maximum quantities and numbers of repeats for brands of pharmaceutical benefits, the deletion of pack quantities for brands of pharmaceutical benefits, the addition of a responsible person to the list of responsible persons, the addition and deletion of pharmaceutical benefits covered under Supply Only arrangements, and the alteration of circumstances for prescribing various pharmaceutical benefits available on the Pharmaceutical Benefits Scheme. These changes are summarised below.

**SUMMARY OF CHANGES TO THE PHARMACEUTICAL BENEFITS SCHEME****MADE BY SCHEDULE 1 OF THIS INSTRUMENT**

**Forms Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Adefovir | Tablet containing adefovir dipivoxil 10 mg (S19A) |
| Essential amino acids formula with vitamins and minerals | Sachets containing oral powder 12.5 g, 30 (EAA Supplement) |
| Morphine | Oral solution containing morphine sulfate 2 mg per mL in 100 mL bottle, 1 mL (S19A) |
| Oral solution containing morphine sulfate 2 mg per mL in 500 mL bottle, 1 mL (S19A) |
| Oral solution containing morphine sulfate 10 mg per 5 mL in 100 mL bottle, 1 mL (S19A) |
| Oral solution containing morphine sulfate 10 mg per 5 mL in 300 mL bottle, 1 mL (S19A) |
| Tofacitinib | Oral solution 1 mg per mL, 240 mL |

**Forms Deleted**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Amoxicillin | Powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A) |
| Colestyramine | Sachet containing 4 g oral powder (s19A) |
| Fentanyl | Lozenge 1200 micrograms (as citrate) |
| Lozenge 1600 micrograms (as citrate) |
| Ibandronic acid | Concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL |
| Pancrelipase | Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity (s19A) |
| Pyridostigmine | Tablet containing pyridostigmine bromide 180 mg (modified release) s19A |
| Ranitidine | Syrup 150 mg (as hydrochloride) per 10 mL, 300 mL |

**Brands Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form and Brand*** |
| Amoxicillin | Capsule 500 mg (as trihydrate) *(Blooms The Chemist Amoxicillin)* |
| Amoxicillin with clavulanic acid | Tablet containing 875 mg amoxicillin (as trihydrate) with 125 mg clavulanic acid (as potassium clavulanate) *(Blooms The Chemist Amoxicillin/Clavulanic Acid 875/125)* |
| Buprenorphine | Transdermal patch 5 mg *(B-Patch)* |
| Transdermal patch 10 mg *(B-Patch)* |
| Transdermal patch 15 mg *(B-Patch)* |
| Transdermal patch 20 mg *(B-Patch)* |
| Clopidogrel | Tablet 75 mg (as hydrogen sulfate) *(Blooms Clopidogrel)* |
| Cyclophosphamide | Powder for injection 500 mg (anhydrous) *(CYCLOPHOSPHAMIDE-REACH)* |
| Powder for injection 1 g (anhydrous) *(CYCLOPHOSPHAMIDE-REACH)* |
| Dabigatran etexilate | Capsule 75 mg (as mesilate) *(PHARMACOR DABIGATRAN)* |
| Capsule 110 mg (as mesilate) *(Dabigatran Sandoz; PHARMACOR DABIGATRAN)* |
| Capsule 150 mg (as mesilate) *(Dabigatran Sandoz; PHARMACOR DABIGATRAN)* |
| Meloxicam | Tablet 7.5 mg *(Meloxicam Viatris)* |
| Metformin | Tablet containing metformin hydrochloride 500 mg *(Blooms The Chemist Metformin 500 mg)* |
| Tablet containing metformin hydrochloride 850 mg *(Blooms The Chemist Metformin 850 mg)* |
| Tablet containing metformin hydrochloride 1 g *(Blooms The Chemist Metformin 1000 mg)* |
| Mycophenolic acid | Tablet (enteric coated) containing mycophenolate sodium equivalent to 360 mg mycophenolic acid *(MYCOTEX)* |
| Nevirapine | Tablet 200 mg *(Nevirapine Viatris)* |
| Olanzapine | Tablet 5 mg (orally disintegrating) *(Zypine ODT)* |
| Tablet 10 mg (orally disintegrating) *(Zypine ODT)* |
| Tablet 15 mg (orally disintegrating) *(Zypine ODT)* |
| Tablet 20 mg (orally disintegrating) *(Zypine ODT)* |
| Olmesartan | Tablet containing olmesartan medoxomil 20 mg *(Blooms The Chemist Olmesartan)* |
| Tablet containing olmesartan medoxomil 40 mg *(Blooms The Chemist Olmesartan)* |
| Olmesartan with amlodipine | Tablet containing olmesartan medoxomil 20 mg with amlodipine 5 mg (as besilate) *(Olmesartan/Amlodipine Sandoz)* |
| Tablet containing olmesartan medoxomil 40 mg with amlodipine 5 mg (as besilate) *(Olmesartan/Amlodipine Sandoz)* |
| Tablet containing olmesartan medoxomil 40 mg with amlodipine 10 mg (as besilate) *(Olmesartan/Amlodipine Sandoz)* |
| Pirfenidone | Tablet 267 mg *(Pirfenidone Ameda)* |
| Tablet 801mg *(Pirfenidone Ameda)* |
| Pregabalin | Capsule 25 mg *(BTC Pregabalin)* |
| Capsule 75 mg *(BTC Pregabalin)* |
| Capsule 150 mg *(BTC Pregabalin)* |
| Capsule 300 mg *(BTC Pregabalin)* |
| Sitagliptin with metformin | Tablet (modified release) containing 50 mg sitagliptin with 1000 mg metformin hydrochloride *(Sitagliptin/Metformin Sandoz XR)* |
| Tablet (modified release) containing 100 mg sitagliptin with 1000 mg metformin hydrochloride *(Sitagliptin/Metformin Sandoz XR)* |

**Brands Deleted**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form and Brand*** |
| Alendronic acid with colecalciferol | Tablet 70 mg (as alendronate sodium) with 70 micrograms colecalciferol *(Alendronate Plus D3 Sandoz)* |
| Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol *(Alendronate Plus D3 Sandoz)* |
| Amisulpride | Tablet 400 mg *(Amisulpride 400 Winthrop)* |
| Amitriptyline | Tablet containing amitriptyline hydrochloride 25 mg *(Amitriptyline Alphapharm 25)* |
| Carboplatin | Solution for I.V. injection 450 mg in 45 mL *(DBL Carboplatin)* |
| Cefepime | Powder for injection 2 g (as hydrochloride) *(Cefepime-AFT)* |
| Entecavir | Tablet 1 mg (as monohydrate) *(ENTAC)* |
| Filgrastim | Injection 300 micrograms in 0.5 mL single-use pre-filled syringe *(Neupogen)* |
| Injection 480 micrograms in 0.5 mL single-use pre-filled syringe *(Neupogen)* |
| Fluorouracil | Injection 2500 mg in 50 mL *(DBL Fluorouracil Injection BP)* |
| Imatinib | Capsule 100 mg (as mesilate) *(CIPLA IMATINIB ADULT)* |
| Capsule 400 mg (as mesilate) *(CIPLA IMATINIB ADULT)* |
| Moxonidine | Tablet 400 micrograms *(Moxonidine MYL)* |
| Nicorandil | Tablets 10 mg, 60 (*Ikorel*) |
| Tablets 20 mg, 60 (*Ikorel*) |
| Octreotide | Injection 500 micrograms (as acetate) in 1 mL *(Octreotide MaxRx)* |
| Olanzapine | Wafer 5 mg *(Zypine ODT)* |
| Wafer 10 mg *(Zypine ODT)* |
| Wafer 15 mg *(Zypine ODT)* |
| Wafer 20 mg *(Zypine ODT)* |
| Oxaliplatin | Solution concentrate for I.V. infusion 100 mg in 20 mL *(DBL Oxaliplatin Concentrate)* |
| Pemetrexed | Powder for I.V. infusion 100 mg (as disodium) *(Pemetrexed-AFT)* |
| Powder for I.V. infusion 500 mg (as disodium) *(Pemetrexed-AFT)* |
| Tobramycin | Injection 80 mg in 2 mL *(DBL Tobramycin)* |
| Vancomycin | Powder for injection 500 mg (500,000 I.U.) (as hydrochloride) *(Vancomycin Viatris)* |
| Powder for injection 1 g (1,000,000 I.U.) (as hydrochloride) *(Vancomycin Viatris)* |
| Voriconazole | Tablet 50 mg (*Vfend*) |

**Addition of Maximum Quantity and Number of Repeats**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Maximum Quantity*** | ***Number of Repeats*** |
| Infliximab | Powder for I.V. infusion 100 mg | *Inflectra; Renflexis* | 5 | 3 |
| Upadacitinib | Tablet 30 mg | *Rinvoq* | 28 | 2 |
| Tablet 45 mg | *Rinvoq* | 28 | 2 |
| Zoledronic acid | Injection concentrate for I.V. infusion 4 mg (as monohydrate) in 5 mL | *Zoledronic Acid Accord* | 1 | 0 |

**Deletion of Maximum Quantity and Number of Repeats**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Maximum Quantity*** | ***Number of Repeats*** |
| Fentanyl | Lozenge 600 micrograms (as citrate) | *Actiq* | 9 | 0 |
| Lozenge 800 micrograms (as citrate) | *Actiq* | 9 | 0 |
| Tablet (orally disintegrating) 400 micrograms (as citrate) | *Fentora* | 8 | 0 |
| Tablet (orally disintegrating) 600 micrograms (as citrate) | *Fentora* | 8 | 0 |
| Tablet (orally disintegrating) 800 micrograms (as citrate) | *Fentora* | 8 | 0 |
| Ondansetron | Wafer 8 mg | *Zofran Zydis* | 4 | 0 |

**Deletion of Pack Quantity**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Pack Quantity*** |
| Riociguat | Tablet 500 micrograms | *Adempas* | 84 |
| Tablet 1 mg | *Adempas* | 84 |
| Tablet 1.5 mg | *Adempas* | 84 |
| Tablet 2 mg | *Adempas* | 84 |
| Tablet 2.5 mg | *Adempas* | 84 |

**Addition of Responsible Persons**

|  |
| --- |
| AU Pharma Pty Ltd *(IU)* |

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

|  |  |
| --- | --- |
| ***Listed Drug*** | |
| Adalimumab | Ixekizumab |
| Bimekizumab | Nivolumab |
| Certolizumab pegol | Pembrolizumab |
| Darolutamide | Secukinumab |
| Durvalumab | Tofacitinib |
| Etanercept | Upadacitinib |
| Golimumab | Zoledronic acid |
| Infliximab |  |

**Supply Only – Additions**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Essential amino acids formula with vitamins and minerals | Sachets containing oral powder 12.5 g, 50 (EAA Supplement) |
| Estradiol with dydrogesterone | Tablet 1 mg-5 mg |
| Filgrastim | Injection 300 micrograms in 1 mL |
| Injection 480 micrograms in 1.6 mL |
| Insulin neutral with insulin isophane | Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 |
| Macrogol 3350 | Oral liquid 13.125 g in 25 mL with electrolytes, 500 mL |
| Pancrelipase | Capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity |
| Raltegravir | Tablet 25 mg (as potassium) |
| Tablet 100 mg (as potassium) |
| Sterculia with frangula bark | Granules 620 mg-80 mg per g, 500 g |

**Supply Only – Deletions**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Labetalol | Tablet containing labetalol hydrochloride 200 mg |

**Documents Incorporated by Reference**

|  |  |  |
| --- | --- | --- |
| ***Listed Drug*** | ***Document incorporated*** | ***Document access*** |
| Adalimumab  Certolizumab pegol  Durvalumab  Etanercept  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | **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> |
| Adalimumab  Certolizumab pegol  Etanercept  Golimumab  Infliximab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | **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](http://www.servicesaustralia.gov.au) |
| Upadacitinib | **Crohn Disease Activity Index (CDAI).**  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 Crohn’s Disease Activity Index (CDAI) is a research tool used to quantify the symptoms of patients with Crohn’s disease. | Crohn Disease Activity Index (CDAI) is available for download for free from the PubMed website:  <https://pubmed.ncbi.nlm.nih.gov/12786607/>  A CDAI score calculation form is included in the Services Australia application form |
| Bimekizumab | **Psoriasis Area Severity Index (PASI).**  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 PASI is a widely used tool that enables measurement of the severity and extent of baseline and response of therapy in psoriasis. | The PASI calculation form is available for download for free from the Services Australia website: <https://www.servicesaustralia.gov.au/> and forms part of the SA authority application process. |
| Durvalumab  Nivolumab | **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*** |
| Adalimumab  Certolizumab pegol  Etanercept  Golimumab  Ixekizumab  Secukinumab  Tofacitinib  Upadacitinib | **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 |

**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. 12)***

**(PB 112 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. 12)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

**Human rights implications**

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

*The Right to Social Security*

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

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

*The Right to Health*

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

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

**Analysis**

The Instrument advances the right to health and the right to social security by providing new forms and brands of existing listed drugs, and ensuring the deletion of forms of listed drugs and brands of listed drugs does not affect access to subsidised medicines. The Pharmaceutical Benefits Scheme (PBS) is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the Schedule are evidence-based. The Instrument includes the addition of 7 new forms of existing drugs, and the addition of 37 new brands across 35 existing forms, which allows for greater patient access to these drugs.

When a sponsor submits a request to delist a drug from the PBS Schedule, 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 amoxicillin in the form powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL (s19A) (Amoxicillin 250mg/5 ml Oral Suspension Sugar Free BP (Kent)) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of amoxicillin in the form powder for oral suspension 250 mg (as trihydrate) per 5 mL, 100 mL. The shortage has been resolved, and the temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. Patient access has not been affected by this delisting, as the approved form of the drug is now available and remains PBS-subsidised and accessible for patients.

The drug colestyramine in the form sachet containing 4 g oral powder (s19A) (JAMP-Cholestyramine) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of colestyramine in the form sachets containing 4.7 g oral powder (equivalent to 4 g colestyramine), 50. The temporary approval granted in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. The Department is considering the listing of another alternative section 19A colestyramine product.

The drug essential amino acids formula with vitamins and minerals in the form sachets containing oral powder 12.5 g, 50 (EAA Supplement) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that the sponsor indicated the manufacture of this product will be discontinued and will no longer be available in Australia. The PBAC noted that the sponsor indicated there would be no interruption in supply, as the listing of a similar new product that was recommended at the November 2021 PBAC meeting would overlap with the delisting of this product. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will be available on the PBS 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 estradiol with dydrogesterone (Femoston-Conti) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there are no suitable PBS-subsidised pharmaceutical alternatives to this drug, as it is the only low dose form of continuous menopausal hormone therapy (MHT) listed on the PBS Schedule. The PBAC noted the sponsor intends to continue supplying this product privately. The PBAC advised the delisting of this product may result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug fentanyl in the forms lozenge 1200 micrograms (as citrate) (Actiq) and lozenge 1600 micrograms (as citrate) (Actiq) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and the multiple alternatives listed on the PBS Schedule. The PBAC advised the delisting of these forms would not result in an unmet clinical need.

The drug filgrastim in the forms injection 300 micrograms in 1 mL (Neupogen) and injection 480 micrograms in 1.6 mL (Neupogen) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and the multiple alternatives listed on the PBS Schedule. The PBAC noted the sponsor anticipated a potential shortage from July 2023 due to diminished supply and that these products will ultimately be de-registered from the Australian Register of Therapeutic Goods. The PBAC advised the delisting of these forms would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 3 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug ibandronic acid in the form concentrated injection for I.V. infusion 6 mg (as ibandronate sodium monohydrate) in 6 mL (Bondronat) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted that there were no services in the last financial year and the multiple alternatives available on the PBS Schedule. The PBAC noted the sponsor indicated that the product has been discontinued from manufacture and also that it has notified the TGA of the discontinuation. The PBAC advised the delisting of this form would not result in an unmet clinical need.

The drug insulin neutral with insulin isophane in the form Injections (human), cartridges, 50 units-50 units per mL, 3 mL, 5 (Mixtard 50/50 Penfill 3 mL) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the previous financial year and the alternatives available on the PBS Schedule. The PBAC noted the sponsor indicated that the product is no longer marketed in Australia and also that it has notified the TGA of the product’s withdrawal from the market. The PBAC advised the delisting of this form would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug labetalol in the form tablet containing labetalol hydrochloride 200 mg (Trandate) has been delisted from the PBS Schedule. This item had been available on the PBS Schedule under Supply Only arrangements for a period of 6 months after its sponsor requested that it be delisted. This arrangement had allowed patients with a pre‑existing valid prescription to access the item through the PBS pending transition to an alternative treatment option. The PBAC had noted that the 100 mg strength of labetalol tablets will remain listed on the PBS Schedule, and advised the delisting of the 200 mg strength tablets would not result in an unmet clinical need.

The drug macrogol 3350 in the form oral liquid 13.125 g in 25 mL with electrolytes, 500 mL (Movicol Liquid) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the substantial number of services in the last financial year and that the sachet form remains listed on the PBS Schedule. The PBAC noted the sponsor’s statement that there would be stock available until the fourth quarter of 2023. The PBAC advised the delisting of this product would not result in an unmet clinical need. This item will remain available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug pancrelipase in the form capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity (Panzytrat 25000) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and that the alternative s19A product is no longer available. The PBAC noted that the sponsor has advised there has been no supply of the product in Australia since November 2020 and that the product, which has now been discontinued, was removed from the ARTG in November 2021. The PBAC reaffirmed its previous advice at the March 2023 PBAC meeting (when this delisting was first considered) that delisting would not result in an unmet clinical need as there is an alternative on the PBS Schedule. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre‑existing valid prescription to access the item pending transition to an alternative treatment option.

The drug pancrelipase in the form capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity (s19A) (Panzytrat 25000) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of pancrelipase in the form capsule (containing enteric coated microtablets) providing not less than 25,000 BP units of lipase activity. Temporary approval in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. The PBAC noted the low number of services in the last financial year. The PBAC reaffirmed its previous advice at the March 2023 PBAC meeting that delisting, and the removal of this drug from the PBS Schedule, would not result in an unmet clinical need.

The drug pyridostigmine in the form tablet containing pyridostigmine bromide 180 mg (modified release) (s19A) (Pyridostigmine Bromide Extended-Release Tablets (Rising)) was requested to be delisted from the PBS Schedule by the sponsor. This item was listed under section 19A of the *Therapeutic Goods Act 1989* to address the shortage of pyridostigmine in the form tablet containing pyridostigmine bromide 180 mg (modified release). The shortage has been resolved and temporary approval in respect of this drug for importation and supply of a medicine not on the Australian Register of Therapeutic Goods has lapsed. Patient access has not been affected as the approved form of the drug is now available and remains PBS-subsidised and accessible for patients.

The drug raltegravir in the forms tablet 25 mg (as potassium) and tablet 100 mg (as potassium) (Isentress) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted there were no services in the last financial year and the multiple alternatives on the PBS Schedule. The PBAC advised the delisting of this form would not result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 6 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option

The drug ranitidine in the form syrup 150 mg (as hydrochloride) per 10 mL, 300 mL (Zantac Syrup) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the low number of services in the last financial year and the multiple alternatives on the PBS Schedule. The PBAC advised the delisting of this product would not result in an unmet clinical need.

The drug sterculia with frangula bark in the form granules 620 mg-80 mg per g, 500 g (Normacol Plus) was requested to be delisted from the PBS Schedule by the sponsor. The PBAC noted the substantial number of services in the previous year and that the product has been discontinued from supply. The PBAC noted this product is the only bulk-forming laxative listed on the PBS Schedule and that no suitable PBS‑subsidised pharmaceutical alternative is available. The PBAC advised the delisting of this product may result in an unmet clinical need. This item will be available on the PBS Schedule under Supply Only arrangements for a period of 4 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

**Conclusion**

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

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**Technology Assessment and Access Division**

**Department of Health and Aged Care**