**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2023 (No. 4)***

**PB 34 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 of the listed drugs abiraterone and methylprednisolone, asciminib, and vosoritide, and the addition of forms of the listed drugs budesonide with formoterol, elexacaftor with tezacaftor and with ivacaftor, and ivacaftor, glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine, upadacitinib, and ustekinumab to the PBS Schedule. It also provides for the alteration of circumstances in which prescriptions may be written for the supply of the listed drugs abiraterone, budesonide, daratumumab, donepezil, galantamine, ipilimumab, lenvatinib, memantine, methylphenidate, naltrexone, nintedanib, nivolumab, olaparib, ozanimod, pembrolizumab, rivastigmine, sacituzumab govitecan, and upadacitinib.

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

* the addition of a brand for an existing pharmaceutical item;
* the deletion of 9 brands of existing pharmaceutical items;
* the addition of a maximum quantity and number of repeats for 6 existing pharmaceutical items;
* the deletion of a maximum quantity and number of repeats for 44 existing pharmaceutical items;
* the alteration of responsible persons code for 11 brands of pharmaceutical items;
* the alteration of an authorised prescriber for an existing pharmaceutical item;
* the addition of 15 pharmaceutical items covered under Supply Only arrangements; and
* the deletion of 7 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 May 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. 4)***

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2023 (No. 4)* and may also be cited as PB 34 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 May 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 listed drugs, the addition 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 alteration of responsible person code for brands of pharmaceutical benefits, the alteration of authorised prescriber for a pharmaceutical benefit, 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**

**Drugs Added**

|  |
| --- |
| ***Listed Drug*** |
| Abiraterone and methylprednisolone |
| Asciminib |
| Vosoritide |

**Forms Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses |
| Elexacaftor with tezacaftor and with ivacaftor, and ivacaftor | Pack containing 56 tablets elexacaftor 50 mg with tezacaftor 25 mg and with ivacaftor 37.5 mg and 28 tablets ivacaftor 75 mg |
| Glycomacropeptide formula with long chain polyunsaturated fatty acids and docosahexaenoic acid and low in phenylalanine | Oral liquid 237 mL, 15 (PKU Sphere Liquid) |
| Upadacitinib | Tablet 45 mg  |
| Ustekinumab | Injection 90 mg in 1 mL single use pre-filled syringe |

**Brand Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form and Brand*** |
| Trimethoprim | Tablet 300 mg *(Trimethoprim Viatris)* |

**Brands Deleted**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form and Brand*** |
| Levodopa with carbidopa and entacapone | Tablet 50 mg-12.5 mg (as monohydrate)-200 mg *(TRIDOPA)* |
| Tablet 75 mg-18.75 mg (as monohydrate)-200 mg *(TRIDOPA)* |
| Tablet 100 mg-25 mg (as monohydrate)-200 mg *(TRIDOPA)* |
| Tablet 125 mg-31.25 mg (as monohydrate)-200 mg *(TRIDOPA)* |
| Tablet 150 mg-37.5 mg (as monohydrate)-200 mg *(TRIDOPA)* |
| Tablet 200 mg-50 mg (as monohydrate)-200 mg *(TRIDOPA)* |
| Norethisterone with ethinylestradiol | Pack containing 21 tablets 1 mg-35 micrograms and 7 inert tablets *(Brevinor-1)* |
| Oxycodone | Capsule containing oxycodone hydrochloride 5 mg *(Oxycodone BNM)* |
| Capsule containing oxycodone hydrochloride 20 mg *(Oxycodone BNM)* |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Maximum Quantity*** | ***Number of Repeats*** |
| Lenvatinib | Capsule 4 mg (as mesilate) | *Lenvima* | 60 | 2 |
| Ozanimod | Capsule 920 micrograms | *Zeposia* | 28 | 3 |
| Pramipexole | Tablet containing pramipexole dihydrochloride monohydrate 125 micrograms | *Simipex 0.125* | 30 | 2 |
| Tablet containing pramipexole dihydrochloride monohydrate 250 micrograms | *Simipex 0.25* | 100 | 2 |
| Upadacitinib | Tablet 15 mg | *Rinvoq* | 28 | 1 |
| Tablet 30 mg | *Rinvoq* | 28 | 1 |

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Maximum Quantity*** | ***Number of Repeats*** |
| Donepezil | Tablet containing donepezil hydrochloride 5 mg | *APO-Donepezil* | 28 | 1 |
| *Arazil* | 28 | 1 |
| *Aricept* | 28 | 1 |
| *Aridon 5* | 28 | 1 |
| *Aridon APN 5* | 28 | 1 |
| *Donepezil GH* | 28 | 1 |
| *Donepezil Sandoz* | 28 | 1 |
| *Donepezil-DRLA* | 28 | 1 |
| *NOUMED DONEPEZIL* | 28 | 1 |
| Tablet containing donepezil hydrochloride 10 mg | *APO-Donepezil* | 28 | 1 |
| *Arazil* | 28 | 1 |
| *Aricept* | 28 | 1 |
| *Aridon 10* | 28 | 1 |
| *Aridon APN 10* | 28 | 1 |
| *Donepezil GH* | 28 | 1 |
| *Donepezil Sandoz* | 28 | 1 |
| *Donepezil-DRLA* | 28 | 1 |
| *NOUMED DONEPEZIL* | 28 | 1 |
| Galantamine | Capsule (prolonged release) 8 mg (as hydrobromide) | *APO-Galantamine MR* | 28 | 1 |
| *Galantyl* | 28 | 1 |
| *Gamine XR* | 28 | 1 |
| *Reminyl* | 28 | 1 |
| Capsule (prolonged release) 16 mg (as hydrobromide) | *APO-Galantamine MR* | 28 | 1 |
| *Galantyl* | 28 | 1 |
| *Gamine XR* | 28 | 1 |
| *Reminyl* | 28 | 1 |
| Capsule (prolonged release) 24 mg (as hydrobromide) | *APO-Galantamine MR* | 28 | 1 |
| *Galantyl* | 28 | 1 |
| *Gamine XR* | 28 | 1 |
| *Reminyl* | 28 | 1 |
| Memantine | Tablet containing memantine hydrochloride 10 mg | *APO-Memantine* | 56 | 1 |
| *Ebixa* | 56 | 1 |
| *Memantine generichealth* | 56 | 1 |
| *Memanxa* | 56 | 1 |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | Tablet containing memantine hydrochloride 20 mg | *APO-Memantine* | 28 | 1 |
| *Ebixa* | 28 | 1 |
| *Memantine generichealth* | 28 | 1 |
| Rivastigmine | Capsule 1.5 mg (as hydrogen tartrate) | *Exelon* | 56 | 1 |
| Capsule 3 mg (as hydrogen tartrate) | *Exelon* | 56 | 1 |
| Capsule 4.5 mg (as hydrogen tartrate) | *Exelon* | 56 | 1 |
| Capsule 6 mg (as hydrogen tartrate) | *Exelon* | 56 | 1 |
| Transdermal patch 9 mg | *Exelon Patch 5* | 30 | 1 |
| Transdermal patch 18 mg | *Exelon Patch 10* | 30 | 1 |
| Transdermal patch 27 mg | *Exelon Patch 15* | 30 | 1 |

**Alteration of Responsible Person Code**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Responsible Person*** |
| Fluticasone propionate | Pressurised inhalation containing fluticasone propionate 50 micrograms per dose, 120 doses (CFC-free formulation) | *Axotide Junior* | From: **GC**  | To: **TX** |
| Pressurised inhalation containing fluticasone propionate 125 micrograms per dose, 120 doses (CFC-free formulation) | *Axotide* | From: **GC**  | To: **TX** |
| Pressurised inhalation containing fluticasone propionate 250 micrograms per dose, 120 doses (CFC-free formulation) | *Axotide* | From: **GC**  | To: **TX** |
| Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms per dose, 60 doses | *Axotide Junior Accuhaler* | From: **GC**  | To: **TX** |
| Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms per dose, 60 doses | *Axotide Accuhaler* | From: **GC**  | To: **TX** |
| Fluticasone propionate with salmeterol | Pressurised inhalation containing fluticasone propionate 50 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | *PAVTIDE MDI 50/25* | From: **GC**  | To: **TX** |
| Pressurised inhalation containing fluticasone propionate 125 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | *Pavtide* | From: **GC**  | To: **TX** |
| Pressurised inhalation containing fluticasone propionate 250 micrograms with salmeterol 25 micrograms (as xinafoate) per dose, 120 doses (CFC-free formulation) | *Pavtide* | From: **GC**  | To: **TX** |
| Powder for oral inhalation in breath actuated device containing fluticasone propionate 100 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | *PAVTIDE ACCUHALER 100/50* | From: **GC**  | To: **TX** |
| Powder for oral inhalation in breath actuated device containing fluticasone propionate 250 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | *PAVTIDE ACCUHALER 250/50* | From: **GC**  | To: **TX** |
| Powder for oral inhalation in breath actuated device containing fluticasone propionate 500 micrograms with salmeterol 50 micrograms (as xinafoate) per dose, 60 doses | *PAVTIDE ACCUHALER 500/50* | From: **GC**  | To: **TX** |

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

|  |
| --- |
| ***Listed Drug*** |
| Abiraterone | Naltrexone |
| Budesonide | Nintedanib |
| Daratumumab | Nivolumab |
| Donepezil | Olaparib |
| Galantamine | Ozanimod |
| Ipilimumab | Pembrolizumab |
| Lenvatinib | Rivastigmine |
| Memantine | Sacituzumab govitecan |
| Methylphenidate | Upadacitinib |

**Alteration of Authorised Prescriber**

|  |  |  |  |
| --- | --- | --- | --- |
| ***Listed Drug*** | ***Form*** | ***Brand Name*** | ***Authorised Prescriber*** |
| Naltrexone | Tablet containing naltrexone hydrochloride 50 mg | *Naltrexone GH* | From: **MP NP** | To: **MP** |

**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*** |
| Budesonide with formoterol | Powder for oral inhalation in breath actuated device containing budesonide 400 micrograms with formoterol fumarate dihydrate 12 micrograms per dose, 60 doses, 2 *(Symbicort Turbuhaler 400/12)* |
| Donepezil | Tablet containing donepezil hydrochloride 5 mg *(APO-Donepezil;* *Arazil; Aricept; Aridon 5; Aridon APN 5; Donepezil GH; Donepezil Sandoz; Donepezil-DRLA; NOUMED DONEPEZIL)* |
| Tablet containing donepezil hydrochloride 10 mg *(APO-Donepezil;* *Arazil; Aricept; Aridon 10; Aridon APN 10; Donepezil GH; Donepezil Sandoz; Donepezil-DRLA; 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)*  |
| 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)* |

**Supply Only – Deletions**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form and Brand*** |
| Ampicillin | Powder for injection 500 mg (as sodium) *(Austrapen)* |
| Hydromorphone | Tablet (modified release) containing hydromorphone hydrochloride 4 mg *(Jurnista)* |
| Tablet (modified release) containing hydromorphone hydrochloride 8 mg *(Jurnista)* |
| Tablet (modified release) containing hydromorphone hydrochloride 16 mg *(Jurnista)* |
| Tablet (modified release) containing hydromorphone hydrochloride 32 mg *(Jurnista)* |
| Tablet (modified release) containing hydromorphone hydrochloride 64 mg *(Jurnista)* |
| Triglycerides, medium chain | Oral liquid 225 mL, 15 (betaquik) *(Betaquik)* |

**Documents Incorporated by Reference**

|  |  |  |
| --- | --- | --- |
| ***Listed Drug*** | ***Document incorporated*** | ***Document access*** |
| DonepezilGalantamineRivastigmine | **Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog)/ Alzheimer’s Disease Assessment Scale for Cognition (ADAS-Cog)**Alzheimer Disease Assessment Scale, cognitive sub-scale (ADAS-Cog). 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 ADAS-Cog is used for comprehensive cognitive assessment and is widely used as an outcome measure in drug and therapy treatments aimed at delaying cognitive decline in dementia. | The ADAS-Cog is available for download for free from the DementiaKT website: <http://dementiakt.com.au/doms/downloads/> |
| DaratumumabOzanimodPembrolizumabUpadacitinibUstekinumabVosoritide | **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> |
| DonepezilGalantamineMemantineRivastigmine | **Clinicians Interview Based Impression of Severity (CIBIS) scale**Clinicians Interview Based Impression of Severity (CIBIS) Scale. 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 CIBIS scale is a semi-structured interview for prescribers to assess a patient’s cognitive function. | The CIBIS Scale is available for download for free from the Yumpu website: <https://www.yumpu.com/en/document/view/6984731/cibis-pfizer>  |
| LenvatinibNivolumabPembrolizumab | **International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma**International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma.  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 International Metastatic RCC Database Consortium (IMDC) Risk Model for Metastatic Renal Cell Carcinoma is a tool used to predict survival in patients with metastatic renal cell carcinoma who are treated with systemic therapy. | The IMDC Risk Model is available for download for free from the MDCalc website: [www.mdcalc.com/calc/3008/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma](http://www.mdcalc.com/calc/3008/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma) |
| OzanimodUpadacitinibUstekinumab | **Mayo clinic score and partial Mayo clinic score**Mayo clinic score and partial Mayo clinic 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 Mayo clinic score and the partial Mayo clinic score (an abbreviated form of the Mayo clinic score) are medical diagnostic tools used to measure disease activity, in a standardised way, in Ulcerative Colitis through the evaluation of symptoms. | The Mayo clinic score and the partial Mayo clinic score are available to download for free from the Inflammatory Bowel Diseases Journal via the Oxford University Press website: <https://academic.oup.com/ibdjournal/article/14/12/1660/4654949?login=true> |
| DonepezilGalantamineMemantineRivastigmine | **Mini-Mental State Examination (MMSE)/ Standardised Mini-Mental State Examination (SMMSE)**The Mini-Mental State Examination (MMSE) or Standardised Mini-Mental State Examination (SMMSE). 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 MMSE is used as a screening test for evaluating cognitive impairment in older adults. The SMMSE provides scoring instructions and clear and unambiguous guidelines for administration of the MMSE tool, in order to increase reliability and reduce variability. | The MMSE/SMME is available for download for free from the Independent Hospital Pricing Authority website: <https://www.ihpa.gov.au/what-we-do/standardised-mini-mental-state-examination-smmse> |
| AbirateroneAbiraterone and methylprednisoloneDaratumumabLenvatinibNivolumabPembrolizumab | **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*** |
| Asciminib | **The international scale for BCR-ABL** | To determine the peripheral blood BCR-ABL level. The BCR - ABL test may be used to see if cancer treatment is effective or if a patient has developed a resistance to certain treatment. That means a treatment that used to be effective is no longer working.  | A BCR-ABL test is most often used to diagnose or rule out chronic myeloid leukemia (CML) or a specific form of acute lymphoblastic leukemia (ALL) called Ph-positive ALL. Ph-positive means a Philadelphia chromosome was found. The test is not used to diagnose other types of leukemia.  |

**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. 4)***

**(PB 34 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. 4)* (the Instrument) amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) (the Principal Instrument) which determines the pharmaceutical benefits that are listed on the Schedule of Pharmaceutical Benefits (the Schedule) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, schedule equivalence, maximum quantities, number of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

**Human rights implications**

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

*The Right to Social Security*

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

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

*The Right to Health*

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

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

**Analysis**

The Instrument advances the right to health and the right to social security by providing new drugs, new forms and brands of existing listed drugs, and ensuring the deletion of 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 three new drugs, the addition of five new forms of existing drugs, and the addition of a brand of an existing form, 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 ampicillin in the form powder for injection 500 mg (as sodium) (Austrapen) was requested to be delisted from the PBS by the sponsor. The PBAC advised that 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 from the market and wished to proceed with the delisting. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug hydromorphone in the forms tablet (modified release) containing hydromorphone hydrochloride 4 mg (Jurnista), tablet (modified release) containing hydromorphone hydrochloride 8 mg (Jurnista), tablet (modified release) containing hydromorphone hydrochloride 16 mg (Jurnista), tablet (modified release) containing hydromorphone hydrochloride 32 mg (Jurnista), and tablet (modified release) containing hydromorphone hydrochloride 64 mg (Jurnista) was requested to be delisted from the PBS by the sponsor. The PBAC advised the delisting of these products may result in an unmet clinical need. The Department sought to retain these products on the PBS in line with this advice, however the sponsor advised they wished to proceed with the delisting as the products were being discontinued from manufacture. These items were available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

The drug triglycerides, medium chain in the form oral liquid 225 mL, 15 (betaquik) (Betaquik) was requested to be delisted from the PBS by the sponsor. This item was available on the Schedule under Supply Only arrangements for a period of up to 12 months, allowing patients with a pre‑existing valid prescription to access this item pending transition to an alternative treatment option.

**Conclusion**

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

**Nikolai Tsyganov**

**Assistant Secretary**

**Pricing and PBS Policy Branch**

**Technology Assessment and Access Division**

**Department of Health and Aged Care**