#### EXPLANATORY STATEMENT

##### **NATIONAL HEALTH ACT 1953**

#### *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2014 (No. 6)*

#### PB 45 of 2014

###### Purpose

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

###### PB 71 of 2012 determines the pharmaceutical benefits that are on the PBS through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, maximum quantities, numbers 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). The Minister may also determine a brand of a pharmaceutical item (subsection 85(6)). 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*

Subsection 88(1) provides that a medical practitioner is authorised to prescribe a pharmaceutical benefit. Section 88 provides that the Minister may determine the pharmaceutical benefits that may be prescribed by different classes of prescribers, including participating dental practitioners (subsection 88(1A)), authorised optometrists (subsection 88(1C)), authorised midwives (subsection 88(1D)) and authorised nurse practitioners (subsection 88(1E)).

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.

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.

*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 PBAC has recommended under subsection 101(4AAD) that the drug be made available only under special arrangements under section 100.

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).

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.

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.

*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 Pharmaceutical Benefits Advisory Committee (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 additions, deletions and changes to drugs, forms, brands, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities, section 100 only status and prescriber bag only status. These changes are summarised, by subject matter, in the Attachment.

###### Consultation

The involvement of interested parties through the membership of PBAC constitutes a formal and ongoing process of consultation. 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 as pharmaceutical benefits.  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 PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC.  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.

###### General

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

This Instrument commences on 1 July 2014.

This Instrument is a legislative instrument for the purposes of the *Legislative Instruments Act 2003.*

###### ATTACHMENT

###### PROVISION BY PROVISION DESCRIPTION OF THE *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENT INSTRUMENT 2014 (No. 6)*

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 6)* and may also be cited as PB 45 of 2014.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 July 2014.

**Section 3 Amendment of the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012)**

This section provides that Schedule 1 amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012).

**Schedule 1 Amendments**

The amendments in Schedule 1 involve additions, deletions and changes to forms, brands, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities and section 100 only status. These changes are summarised below.

###### SUMMARY OF CHANGES

**Forms Added**

|  |  |
| --- | --- |
| Bimatoprost with timolol | Eye drops 300 micrograms bimatoprost with timolol 5 mg (as maleate) per mL, single dose units 0.4 mL, 30 |

**Forms Deleted**

|  |  |
| --- | --- |
| Nicotine | Transdermal patch 24.9 mg |

**Brands Added**

|  |  |
| --- | --- |
| Candesartan with Hydrochlorothiazide | Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (Adesan HCT 32/12.5) Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (Adesan HCT 32/25) |
| Cefepime | Powder for injection 1 g (as hydrochloride) (Cefepime Alphapharm) Powder for injection 2 g (as hydrochloride) (Cefepime Alphapharm) |
| Clarithromycin | Tablet 250 mg (Clarihexal) |
| Lamotrigine | Tablet 5 mg (Lamotrigine Aspen 5) |
| Latanoprost | Eye drops 50 micrograms per mL, 2.5 mL (Latanoprost GH) |
| Latanoprost with timolol | Eye drops 50 micrograms latanoprost with timolol 5 mg (as maleate) per mL, 2.5 mL (APO-Latanoprost/Timolol 0.05/5) |
| Memantine | Tablet containing memantine hydrochloride 20 mg (APO-Memantine) |
| Mirtazapine | Tablet 15 mg (orally disintegrating) (Mirtazapine Sandoz ODT 15) Tablet 30 mg (orally disintegrating) (Mirtazapine Sandoz ODT 30) Tablet 45 mg (orally disintegrating) (Mirtazapine Sandoz ODT 45) |
| Pantoprazole | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) (Pantoprazole Actavis) |
| Rosuvastatin | Tablet 5 mg (as calcium) (Rosuvastatin-DRLA) Tablet 10 mg (as calcium) (Rosuvastatin-DRLA) Tablet 20 mg (as calcium) (Rosuvastatin-DRLA) Tablet 40 mg (as calcium) (Rosuvastatin-DRLA) |
| Sumatriptan | Tablet 50 mg (as succinate) (Sumatran) |
| Telmisartan with amlodipine | Tablet 40 mg-5 mg (as besylate) (Pritor/Amlodipine) Tablet 40 mg-10 mg (as besylate) (Pritor/Amlodipine) Tablet 80 mg-5 mg (as besylate) (Pritor/Amlodipine) Tablet 80 mg-10 mg (as besylate) (Pritor/Amlodipine) |

**Brands Deleted**

|  |  |
| --- | --- |
| Ciprofloxacin | Tablet 250 mg (as hydrochloride) (Cifran) |
| Diltiazem | Tablet containing diltiazem hydrochloride 60 mg (Coras) |
| Docetaxel | Solution concentrate for I.V. infusion 20 mg in 1 mL (Oncotaxel 20) |
| Doxycycline | Tablet 50 mg (as monohydrate) (Doxyhexal) Tablet 100 mg (as monohydrate) (Doxyhexal) |
| Fosinopril with Hydrochlorothiazide | Tablet containing fosinopril sodium 10 mg with hydrochlorothiazide 12.5 mg (Hyforil) Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg (Hyforil) |
| Glucose | I.V. infusion 278 mmol (anhydrous) per L, 1 L (Fresenius Kabi Australia Pty Limited) |
| Irinotecan | I.V. injection containing irinotecan hydrochloride trihydrate 40 mg in 2 mL (Irinotecan Actavis) |
| Quetiapine | Tablet 25 mg (as fumarate) (Quipine) Tablet 100 mg (as fumarate) (Quipine) Tablet 200 mg (as fumarate) (Quipine) Tablet 300 mg (as fumarate) (Quipine) |
| Simvastatin | Tablet 10 mg (Simvastatin-Spirit 10) Tablet 20 mg (Simvastatin-Spirit 20) Tablet 40 mg (Simvastatin-Spirit 40) Tablet 80 mg (Simvastatin-Spirit 80) |
| Sodium Chloride | I.V. infusion 154 mmol per L. 1 L (Fresenius Kabi Australia Pty Limited) |
| Sodium Lactate Compound | I.V. infusion containing approximately 131 mmol sodium (as lactate and chloride), 5 mmol potassium (as chloride), 2 mmol calcium (as chloride), 29 mmol bicarbonate (as lactate) and 111 mmol chloride per L, 1 L (Fresenius Kabi Australia Pty Limited) |
| Tramadol | Capsule containing tramadol hydrochloride 50 mg (Lodam 50) |

**Alteration of Brand Name**

|  |  |  |
| --- | --- | --- |
| **Listed Drug** | **Form** | **Brand Name** |
| Atorvastatin and ezetimibe | Pack containing 30 tablets atorvastatin 10 mg (as calcium) and 30 tablets ezetimibe 10 mg  Pack containing 30 tablets atorvastatin 20 mg (as calcium) and 30 tablets ezetimibe 10 mg Pack containing 30 tablets atorvastatin 40 mg (as calcium) and 30 tablets ezetimibe 10 mg Pack containing 30 tablets atorvastatin 80 mg (as calcium) and 30 tablets ezetimibe 10 mg | *From:* Atozet Composite Pack 10mg + 10mg *To:* Atozet Composite Pack *From:* Atozet Composite Pack 10mg + 20mg *To:* Atozet Composite Pack *From:* Atozet Composite Pack 10mg + 40mg *To:* Atozet Composite Pack *From:* Atozet Composite Pack 10mg + 80mg *To:* Atozet Composite Pack |

**Alteration of Responsible Person**

|  |  |  |  |
| --- | --- | --- | --- |
| **Listed Drug** | **Form** | **Brand Name** | **Responsible Person** |
| Acitretin | Capsule 10 mg Capsule 25 mg | Neotigason Neotigason | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
| Clopidogrel | Tablet 75 mg (as besilate) | Clopidogrel Actavis | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
| Diphenoxylate with Atropine | Tablet containing diphenoxylate hydrochloride 2.5 mg with atropine sulfate 25 micrograms | Lofenoxal | From: Biotech Pharmaceuticals Pty Ltd (HC) To: iNova Pharmaceuticals (Australia) Pty Limited (IA) |
|  |  | Lomotil | From: Biotech Pharmaceuticals Pty Ltd (BI) To: iNova Pharmaceuticals (Australia) Pty Limited (IV) |
| Docetaxel | Solution concentrate for I.V. infusion 80 mg in  4 mL | Oncotaxel 80 | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (GN) |
|  | Solution concentrate for I.V. infusion 140 mg in  7 mL | Oncotaxel 140 |  |
| Epirubicin | Solution for injection containing epirubicin hydrochloride 10 mg in 5 mL | Epirubicin Actavis 10 | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
|  | Solution for injection containing epirubicin hydrochloride 20 mg in 10 mL | Epirubicin Actavis 20 |  |
|  | Solution for injection containing epirubicin hydrochloride 50 mg in 25 mL | Epirubicin Actavis 50 |  |
|  | Solution for injection containing epirubicin hydrochloride 200 mg in 100 mL | Epirubicin Actavis 200 |  |
| Fludarabine | Powder for I.V. injection containing fludarabine phosphate 50 mg | Fludarabine Actavis | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
| Irinotecan | I.V. injection containing irinotecan hydrochloride trihydrate 100 mg in 5 mL | Irinotecan Actavis | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
|  | I.V. injection containing irinotecan hydrochloride trihydrate 500 mg in  25 mL | Irinotecan Actavis 500 |  |
| Lamotrigine | Tablet 25 mg Tablet 50 mg Tablet 100 mg Tablet 200 mg | Torlemo DT 25 Torlemo DT 50 Torlemo DT 100 Torlemo DT 200 | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
| Letrozole | Tablet 2.5 mg | Letrozole Actavis | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (VN) |
| Oxaliplatin | Powder for I.V. infusion 50 mg | Oxaliplatin Actavis | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
|  | Powder for I.V. infusion 100 mg | Oxaliplatin Actavis |  |

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| --- | --- | --- | --- |
| Paclitaxel | Solution concentrate for I.V. infusion 30 mg in 5 mL | Paclitaxel Actavis | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
|  | Solution concentrate for I.V. infusion 100 mg in 16.7 mL | Paclitaxel Actavis |  |
|  | Solution concentrate for I.V. infusion 150 mg in 25 mL | Paclitaxel Actavis |  |
|  | Solution concentrate for I.V. infusion 300 mg in 50 mL | Paclitaxel Actavis |  |
| Pantoprazole | Tablet (enteric coated) 20 mg (as sodium sesquihydrate) | Torzole 20 | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (VN) |
|  | Tablet (enteric coated) 40 mg (as sodium sesquihydrate) | Torzole 40 |  |
| Pravastatin | Tablet containing pravastatin sodium 10 mg | Pravastatin Actavis 10 | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (UA) |
|  | Tablet containing pravastatin sodium 20 mg | Pravastatin Actavis 20 |  |
|  | Tablet containing pravastatin sodium 40 mg | Pravastatin Actavis 40 |  |
| Quetiapine | Tablet 25 mg (as fumarate) | Quetiapine Actavis 25 | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (VN) |
|  | Tablet 100 mg (as fumarate) | Quetiapine Actavis 100 |  |
|  | Tablet 200 mg (as fumarate) | Quetiapine Actavis 200 |  |
|  | Tablet 300 mg (as fumarate) | Quetiapine Actavis 300 |  |
| Reteplase | Pack containing 2 vials powder for injection  10 units, 2 single use  pre-filled syringes with solvent, 2 reconstitution spikes and 2 needles | Rapilysin 10 U | From: Actavis Australia Pty Ltd (TA)  To: Actavis Pty Ltd (GN) |

**Alteration of Maximum Quantity and Number of Repeats**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Listed Drug** | **Form** | **Brand** | **Max Qty** | **No. of Rpts** |
| Octreotide | Injection (modified release) 10 mg (as acetate), vial and diluent syringe | Sandostatin LAR | *From:* 1  *To:* 2 | *From:* 11 *To:* 5 |
|  | Injection (modified release) 20 mg (as acetate), vial and diluent syringe | Sandostatin LAR | *From:* 1 *To:* 2 | *From:* 11 *To:* 5 |
|  | Injection (modified release) 30 mg (as acetate), vial and diluent syringe | Sandostatin LAR | *From:* 1 *To:* 2 | *From:* 11 *To:* 5 |

**Alteration of Number of Repeats**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Listed Drug** | **Form** | **Brand** | | **No. of Rpts** | |
| Lanreotide | Injection 60 mg (as acetate) in single dose pre-filled syringe | Somatuline Autogel | *From:* 11 *To:* 5 | |
|  | Injection 90 mg (as acetate) in single dose pre-filled syringe | Somatuline Autogel | *From:* 11 *To:* 5 | |
|  | Injection 120 mg (as acetate) in single dose pre-filled syringe | Somatuline Autogel | *From:* 11 *To:* 5 | |

**Addition of Responsible Person Code**

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| --- |
| iNova Pharmaceuticals (Australia) Pty Limited [IV] |

**Deletion of Responsible Person Code**

|  |
| --- |
| Actavis Australia Pty Limited [TA] |
| Biotech Pharmaceuticals Pty Ltd [BI] |
| Biotech Pharmaceuticals Pty Ltd [HC] |

**Alteration of Circumstances**

|  |  |
| --- | --- |
| **Listed Drug** | **Alteration** |
| Ivermectin | Circumstances amended to extend availability for the treatment of crusted (norwegian) scabies and human sarcoptic scabies |
| Octreotide | Circumstances amended to replace sandostatin subcutaneous injections with octreotide immediate release injections for controlling symptoms |

**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 2014  
(No. 6)***

***(PB 45 of 2014)***

This Legislative 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 Legislative Instrument**

The *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014   
(No. 6)*amends the*National Health (Listing of Pharmaceutical Benefits) Instrument 2012*which determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. It also provides for related matters (responsible persons, prescribing circumstances, maximum quantities, numbers of repeats, determined quantities, pack quantities, section 100 only status and prescriber bag only status).

Schedule 1 to this instrument provides for additions, deletions and changes to drugs, forms, brands, responsible person codes, maximum quantities, the circumstances for prescribing various pharmaceutical benefits (including authority requirements), determined quantities, pack quantities, section 100 only status and prescriber bag only status.

**Human rights implications**

This legislative instrument engages Articles 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

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

**Conclusion**

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

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