#### EXPLANATORY STATEMENT

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

#### *NATIONAL HEALTH (LISTING OF PHARMACEUTICAL BENEFITS) AMENDMENTINSTRUMENT 2014 (No. 5)*

#### PB 36 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 June 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. 5)*

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2014 (No. 5)* and may also be cited as PB 36 of 2014.

**Section 2 Commencement**

This section provides that this Instrument commences on 1 June 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

**Listed Drugs Added**

|  |
| --- |
| Ferric carboxymaltose |
| Tapentadol |

**Forms Added**

|  |  |
| --- | --- |
| Arginine with carbohydrate | Sachets of oral powder 7.6 g containing 5 g arginine, 30 (Arginine 5000) |
| Glucose Indicator—Blood | Test strips, 100 (GoodLife) |

**Brands Added**

|  |  |
| --- | --- |
| Alendronic acid with colecalciferol | Tablet 70 mg (as alendronate sodium) with 140 micrograms colecalciferol (Fonat Plus) |
| Amlodipine with Atorvastatin | Tablet 5 mg amlodipine (as besylate) with 10 mg atorvastatin (as calcium) (Cadivast 5/10)Tablet 5 mg amlodipine (as besylate) with 20 mg atorvastatin (as calcium) (Cadivast 5/20)Tablet 5 mg amlodipine (as besylate) with 40 mg atorvastatin (as calcium) (Cadivast 5/40)Tablet 5 mg amlodipine (as besylate) with 80 mg atorvastatin (as calcium) (Cadivast 5/80)Tablet 10 mg amlodipine (as besylate) with 10 mg atorvastatin (as calcium) (Cadivast 10/10)Tablet 10 mg amlodipine (as besylate) with 20 mg atorvastatin (as calcium) (Cadivast 10/20)Tablet 10 mg amlodipine (as besylate) with 40 mg atorvastatin (as calcium) (Cadivast 10/40)Tablet 10 mg amlodipine (as besylate) with 80 mg atorvastatin (as calcium) (Cadivast 10/80) |
| Candesartan | Tablet containing candesartan cilexetil 4 mg (Chem mart Candesartan; Terry White Chemists Candesartan)Tablet containing candesartan cilexetil 8 mg (Chem mart Candesartan; Terry White Chemists Candesartan)Tablet containing candesartan cilexetil 16 mg (Chem mart Candesartan; Terry White Chemists Candesartan)Tablet containing candesartan cilexetil 32 mg (Chem mart Candesartan; Terry White Chemists Candesartan) |
| Candesartan with Hydrochlorothiazide | Tablet containing candesartan cilexetil 16 mg with hydrochlorothiazide 12.5 mg (Chem mart Candesartan HCTZ 16/12.5; Terry White Chemists Candesartan HCTZ 16/12.5)Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 12.5 mg (Chem mart Candesartan HCTZ 32/12.5; Terry White Chemists Candesartan HCTZ 32/12.5)Tablet containing candesartan cilexetil 32 mg with hydrochlorothiazide 25 mg (Chem mart Candesartan HCTZ 32/25; Terry White Chemists Candesartan HCTZ 32/25) |
| Codeine with Paracetamol | Tablet containing codeine phosphate 30 mg with paracetamol 500 mg (Paracetamol/Codeine GH 500/30) |
| Diltiazem | Tablet containing diltiazem hydrochloride 60 mg (Diltiazem Actavis) |
| Enalapril | Tablet containing enalapril maleate 5 mg (Enalapril Actavis)Tablet containing enalapril maleate 10 mg (Enalapril Actavis) |
| Exemestane | Tablet 25 mg (Exemestane GH) |
| Lamotrigine | Tablet 50 mg (Lamotrigine Aspen 50) |
| Rabeprazole | Tablet containing rabeprazole sodium 20 mg (enteric coated) (Rabeprazole RBX) |
| Risperidone | Tablet 2 mg (Risperidone Actavis 2)Tablet 3 mg (Risperidone Actavis 3) |

**Brands Deleted**

|  |  |
| --- | --- |
| Gemfibrozil | Tablet 600 mg (Lopid) |
| Lactulose | Solution BP 3.34 g per 5 mL, 500 mL (Lac-Dol) |
| Mycophenolic Acid | Capsule containing mycophenolate mofetil 250 mg (Imulate)Tablet containing mycophenolate mofetil 500 mg (Imulate) |

**Alteration of Form Description, Maximum Quantity and Pack Quantity**

|  |  |  |  |
| --- | --- | --- | --- |
| **Listed Drug** | **Form** | **Max Qty** | **Pack Qty** |
| Phenoxybenzamine | *From:* Capsules containing phenoxybenzamine hydrochloride 10 mg, 100*To:* Capsule containing 10 mg phenoxybenzamine hydrochloride | *From:* 1*To:* 100 | *From:* 1*To:* 100 |

**Alteration of Brand Name and Responsible Person Code**

|  |  |  |  |
| --- | --- | --- | --- |
| **Listed Drug** | **Form** | **Brand Name** | **Responsible Person** |
| Epirubicin | Solution for injection containing epirubicin hydrochloride 100 mg in 50 mL | *From:* Epirubicin Actavis 100*To:* Epirubicin ACT | *From:* Actavis Pty Ltd (TA)*To:* Actavis Pty Ltd (VN) |

**Alteration of Responsible Person**

|  |  |  |  |
| --- | --- | --- | --- |
| **Listed Drug** | **Form** | **Brand Name** | **Responsible Person** |
| Nandrolone Decanoate | Injection 50 mg in 1 mL disposable syringe | Deca-Durabolin | *From:* Merck Sharp & Dohme (Australia) Pty Ltd (MK)*To:* Aspen Pharmacare Australia Pty Limited (AS) |
| Oestriol | Pessaries 500 micrograms, 15Vaginal cream 1 mg per g, 15 g | Ovestin OvulaOvestin | *From:* Merck Sharp & Dohme (Australia) Pty Ltd (MK)*To:* Aspen Pharmacare Australia Pty Limited (AS) |

**Addition of Responsible Person Code**

|  |
| --- |
| JNS Biomedical Pty Ltd [JN] |
| Vifor Pharma Pty Limited [VL] |

**Alteration of Circumstances**

|  |  |
| --- | --- |
| **Listed Drug** | **Alteration**  |
| Everolimus | Circumstances amended to extend availability for the treatment of metastatic (Stage IV) breast cancer |
| Exemestane | Circumstances amended to extend availability for the treatment of metastatic (Stage IV) breast cancer |

**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. 5)***

***(PB 36 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. 5)*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.

**Felicity McNeill
First Assistant Secretary
Pharmaceutical Benefits Division
Department of Health**