

## EXPLANATORY STATEMENT

### *National Health Act 1953*

### *National Health (Listing of Pharmaceutical Benefits)*

### *Amendment Instrument 2011 (No. 3)*

### **PB 14 of 2011**

#### **Purpose**

This legislative instrument provides for amendments to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS). It provides for additions, deletions and changes to drugs, forms, brands, responsible persons, authorised prescribers, circumstances for prescribing, and to the maximum quantities and number of repeats that may be prescribed.

#### **Instrument amends PB 108 of 2010**

This Instrument amends the *National Health (Listing of Pharmaceutical Benefits) Instrument 2010* (PB 108 of 2010) (the PBS listing instrument) which commenced on 1 December 2010. The PBS listing instrument contains:

- declarations under subsections 85(2), 85(2A) and 101(4AAA) of the *National Health Act 1953* (the Act); and
- determinations under subsections 84AF(1), 85(3), (5), (6), (7), (8), 85A(2), 88(1A), (1C), (1D) and (1E) of the Act.

The PBS listing instrument determines the pharmaceutical benefits that are on the PBS (through declarations of drugs and medicinal preparations, and for ready-prepared benefits: determinations of forms, manners of administration and brands). It also provides for related matters (responsible persons, authorised prescribers, prescribing circumstances, maximum quantities and numbers of repeats, and whether the pharmaceutical benefit is to be available generally or available only under special arrangements).

#### **Changes to the PBS effected by this Instrument**

Schedule 1 to this Instrument lists the Zelitrex® brand of the drug valaciclovir, tablet 500 mg (as hydrochloride) with an oral manner of administration (the relevant pharmaceutical benefit), as a pharmaceutical benefit. Schedule 1 is taken to have commenced on 1 February 2011 and is therefore retrospective in operation.

The relevant pharmaceutical benefit was listed on the PBS on 1 February 2011 by the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2011 (No. 2)* (PB 1 of 2011). PB 1 of 2011 amended the PBS Listing Instrument to determine, among other things, new brands of pharmaceutical items to be listed as pharmaceutical benefits from 1 February 2011.

However, due to a misdescription in item 44 of PB 1 of 2011, the amendment to add the relevant pharmaceutical benefit could not be incorporated into the official compilation of the PBS Listing Instrument.

No persons are disadvantaged or have any liabilities imposed on them by this amendment being retrospective. The misdescription in PB 1 of 2011 did not prevent the relevant pharmaceutical benefit from being listed as a pharmaceutical benefit on the PBS from 1 February 2011 and it has been treated as such since that date.

Schedule 2 provides for changes made to the PBS commencing on 1 March 2011. The changes made to the PBS by Schedule 2 are summarised, by subject matter, in Attachment 2.

### **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, and agreement to final listing details.

### **This Instrument**

A provision by provision description of this Instrument is contained in Attachment 1.

Sections 1 to 3 and Schedule 1 to this Instrument are taken to have commenced on 1 February 2011.

Schedule 2 to this Instrument commences on 1 March 2011.

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

**PROVISION BY PROVISION DESCRIPTION OF INSTRUMENT**

**Section 1 Name of Instrument**

This section provides that the Instrument is the *National Health (Listing of Pharmaceutical Benefits) Amendment Instrument 2011 (No. 3)* and may also be cited as PB 14 of 2011.

**Section 2 Commencement**

This section provides that sections 1 to 3 and Schedule 1 to this Instrument are taken to have commenced on 1 February 2011 and are therefore retrospective in operation. It also provides that Schedule 2 to this Instrument commences on 1 March 2011.

**Section 3 Amendment of PB 108 of 2010**

This section provides that Schedules 1 and 2 to the Instrument amend PB 108 of 2010.

**Schedules 1 and 2 Amendments**

Schedules 1 and 2 set out the amendments to PB 108 of 2010. These amendments are summarised in Attachment 2.



Naltrexone	Tablet containing naltrexone hydrochloride 50 mg (Naltrexone QP)
Pindolol	Tablet 5 mg (Visken 5)
Ranitidine	Tablet 150 mg (as hydrochloride) (Ranihexal)
Salbutamol	Nebuliser solution 2.5 mg (as sulfate) in 2.5 mL single dose units, 30 (Pfizer Australia Pty Ltd)

### Alteration of Description of Form

Listed Drug	Alteration
Amino acid formula with vitamins and minerals without lysine and low in tryptophan	<i>From:</i> Sachets containing oral powder 20 g, 30 (GA gel) <i>To:</i> Sachets containing oral powder 24 g, 30 (GA gel)
Amino acid formula with vitamins and minerals without methionine	<i>From:</i> Sachets containing oral powder 20 g, 30 (HCU gel) <i>To:</i> Sachets containing oral powder 24 g, 30 (HCU gel)
Amino acid formula with vitamins and minerals without methionine, threonine and valine and low in isoleucine	<i>From:</i> Sachets containing oral powder 20 g, 30 (MMA/PA gel) <i>To:</i> Sachets containing oral powder 24 g, 30 (MMA/PA gel)
Amino acid formula with vitamins and minerals without phenylalanine	<i>From:</i> Sachets containing oral powder 20 g, 30 (PKU-gel) <i>To:</i> Sachets containing oral powder 24 g, 30 (PKU gel)
Amino acid formula with vitamins and minerals without phenylalanine and tyrosine	<i>From:</i> Sachets containing oral powder 20 g, 30 (TYR gel) <i>To:</i> Sachets containing oral powder 24 g, 30 (TYR gel)
Amino acid formula with vitamins and minerals without valine, leucine and isoleucine	<i>From:</i> Sachets containing oral powder 20 g, 30 (MSUD-gel) <i>To:</i> Sachets containing oral powder 24 g, 30 (MSUD gel)
“BCG Immunotherapeutic” (Bacillus Calmette-Guérin/Connaught strain)	<i>From:</i> Single set comprising 1 vial powder for intravesical administration containing 6.6 to 19.2 x 10 <sup>8</sup> CFU and 1 vial diluent 3 mL <i>To:</i> Powder for intravesical administration containing 6.6 to 19.2 x 10 <sup>8</sup> CFU

### Alteration of Maximum Quantity

Listed Drug	Form	Alteration
Mesalazine	Sachet containing prolonged release granules, 1 g per sachet	<i>From:</i> 100 <i>To:</i> 120

### Alteration of Brand

<b>Listed Drug</b>	<b>Form</b>	<b>Alteration</b>
Methadone	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 200 mL	<i>From:</i> Sigma Pharmaceuticals (Australia) Pty Ltd <i>To:</i> Sigma Methadone Syrup
	Oral liquid containing methadone hydrochloride 25 mg per 5 mL, 1 L	<i>From:</i> Sigma Pharmaceuticals (Australia) Pty Ltd <i>To:</i> Sigma Methadone Syrup
Tramadol	Tablet (sustained release) containing tramadol hydrochloride 100 mg	<i>From:</i> TramaHexal SR <i>To:</i> Tramadol Sandoz SR

### Alteration of Brand and Responsible Person

<b>Listed Drug</b>	<b>Form</b>	<b>Brand</b>	<b>Alteration</b>
Norfloxacin	Tablet 400 mg	<i>From:</i> Ascent Pharmaceuticals Limited	<i>From:</i> Ascent Pharmaceuticals Limited (GN)
		<i>To:</i> Norfloxacin-GA	<i>To:</i> Ascent Pharma Pty Ltd (GM)

### Alteration of Authorised Prescriber

<b>Listed Drug</b>	<b>Form</b>	<b>Alteration</b>
Codeine	Tablet containing codeine phosphate 30 mg	Allowance to prescribe extended to authorised Nurse Practitioners
Palonosetron	Injection 250 micrograms (as hydrochloride) in 5 mL	Allowance to prescribe extended to authorised Nurse Practitioners
Vildagliptin	Tablet 50 mg	Allowance to prescribe extended to authorised Nurse Practitioners

### Alteration of Circumstances

<b>Listed Drug</b>	<b>Alteration</b>
Adalimumab	Circumstances amended to remove circumstances (Initial 3)
Bicalutamide	Circumstances amended
Bortezomib	Circumstances amended
Cinacalcet	Circumstances amended to add Streamlined Authority Code
Erlotinib	Circumstances amended to remove circumstances
Exenatide	Circumstances amended
Flutamide	Circumstances amended
Nilutamide	Circumstances amended
Ustekinumab	Circumstances amended to remove circumstances (Initial 3)