

EXPLANATORY STATEMENT

National Health Act 1953

National Health (Listing of Pharmaceutical Benefits)

Amendment Instrument 2011 (No. 5)

PB 31 of 2011

Purpose

This legislative instrument provides for amendments to the pharmaceutical benefits listed on the Pharmaceutical Benefits Scheme (PBS) commencing on 1 May 2011. It provides for additions, deletions and changes to forms, brands, responsible persons, 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 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(4AA) 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, prescribing circumstances, maximum quantities and numbers of repeats, and whether the pharmaceutical benefit is to be available generally or available only under special arrangements).

The Pharmaceutical Benefits Scheme and the powers exercised in the PBS listing instrument

- **Overview**

Part VII of the Act is the legislative basis for the PBS under which Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

Subsection 85(1) of the Act provides that benefits are to be provided by the Commonwealth in accordance with Part VII in respect of pharmaceutical benefits.

Other provisions of Part VII provide for the Minister to make declarations and determinations, by legislative instrument, defining those pharmaceutical benefits and matters relating to the prescribing of those benefits. These are the powers exercised in the PBS listing instrument and they are explained below.

- **Minister's powers – drugs and medicinal preparations, forms, manners of administration and brands**

The Minister's powers to declare drugs and medicinal preparations under subsection 85(2) of the Act, and to determine forms, manners of administration and brands under subsections 85(3), (5) and (6) respectively, are exercised in the PBS listing instrument.

Subsection 85(2) provides for the drugs and medicinal preparations to which Part VII applies. Part VII applies to the drugs and medicinal preparations declared by the Minister under paragraph 85(2)(a). Part VII also applies to certain extemporaneously-prepared medicinal preparations as a result of declarations under paragraph 85(2)(b). All of the drugs and medicinal preparations in relation to which a declaration is in force under subsection 85(2) are defined as *listed drugs*.

The Minister may not declare, under paragraph 85(2)(a), a drug or medicinal preparation to be a drug or medicinal preparation in relation to which Part VII applies unless the Pharmaceutical Benefits Advisory Committee (PBAC) has recommended to the Minister that it be so declared (subsection 101(4)).

The Minister may determine:

- the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3) of the Act);
- the manner of administration of a form of a listed drug (subsection 85(5) of the Act); and
- a brand of a pharmaceutical item (subsection 85(6) of the Act). The pharmaceutical item is the listed drug in the form with the manner of administration determined (section 84AB).

For ready-prepared pharmaceutical benefits, these declarations and determinations govern what is a *pharmaceutical benefit* under the definition of that term in subsection 84(1) of the Act. Where a drug has been declared under subsection 85(2), and a form, manner of administration and brand determined under subsections 85(3), (5) and (6) respectively, the pharmaceutical benefit is that brand of the drug in that form with that manner of administration.

For extemporaneously-prepared pharmaceutical benefits, there are no declarations of form, manner of administration or brand under subsections 85(3), (5) and (6). The pharmaceutical benefit is the drug or medicinal preparation in relation to which there is a declaration under subsection 85(2).

- **Minister's powers – responsible persons**

The Minister may determine the responsible person for a brand of a pharmaceutical item (subsection 84AF(1) of the Act). The brand must be a listed brand, ie, a brand of a pharmaceutical item in relation to which there is a determination under subsection 85(6) in force. The responsible person must be the person who has notified the Minister that they are, or will be, the person who is, or will be, the supplier of a particular brand of a pharmaceutical item to wholesalers, or in cases where no wholesalers are involved, to approved pharmacists directly. The same person must be the responsible person for all pharmaceutical items that have that brand.

- **Minister's powers – prescribing of pharmaceutical benefits**

The Minister's powers to determine authorised prescribers, prescribing circumstances, and maximum quantities and number of repeats that may be prescribed, under section 88, and subsections 85(7) and 85A(2) of the Act, respectively, are exercised in the PBS listing instrument.

Section 88 provides for various matters relating to the prescribing of pharmaceutical benefits. Subsection 88(1) provides that, subject to Part VII, a medical practitioner is authorised to write a prescription for the supply of a pharmaceutical benefit. Other subsections of section 88 empower the Minister to determine the pharmaceutical benefits that may be prescribed by the various categories of prescribers mentioned. The prescribers and the relevant subsections are:

- participating dental practitioners (subsection 88(1A));
- authorised optometrists (subsection 88(1C));
- authorised midwives (subsection 88(1D)); and
- authorised nurse practitioners (subsection 88(1E)).

The Minister may determine the circumstances in which a prescription may be written for the supply of a pharmaceutical benefit (paragraph 85(7)(b)), after determining (under paragraph 85(7)(a)) that the pharmaceutical benefit is a *relevant pharmaceutical benefit* for the purposes of section 88A. Section 88A provides that the writing of a prescription for a relevant pharmaceutical benefit is authorised only in the circumstances determined under subsection 85(7).

The Minister may determine the maximum quantity or number of units of a pharmaceutical benefit or pharmaceutical item that may be directed to be supplied, and the maximum number of occasions on which the supply may be directed to be repeated, in the one prescription (subsection 85A(2)). The determinations may be made with respect to the writing of prescriptions by persons included in a specified class of persons (ie, particular prescribers), and the maximums may be specified for all purposes or particular purposes.

- **Minister's powers – Section 100 only supply**

The Minister's powers in subsection 85(2A) and paragraphs 85(8)(a) and (b) of the Act in relation to section 100 only supply of pharmaceutical benefits are exercised in the PBS listing instrument.

All pharmaceutical benefits are supplied under Part VII of the Act. While most pharmaceutical benefits are generally available for supply under Part VII, some pharmaceutical benefits can, under section 85AA, only be supplied under Part VII in accordance with special arrangements under section 100 of the Act. The section 100 special arrangements are contained in separate instruments. The pharmaceutical benefits to which section 85AA applies are those to which the following Ministerial declarations or determinations relate:

- a declaration that a particular drug or medicinal preparation can only be supplied under special arrangements under section 100 (subsection 85(2A));
- a determination that a particular pharmaceutical benefit can only be supplied under special arrangements under section 100 (paragraph 85(8)(a));
- a determination that one or more of the circumstances (being circumstances determined under paragraph 85(7)(b)) in which a prescription for the supply of the pharmaceutical benefit may be written are circumstances in which the benefit can only be supplied under special arrangements under section 100 (paragraph 85(8)(b)).

- **Minister's powers – revocation of drug declarations**

Subsection 100(4AAA) of the Act empowers the Minister, by legislative instrument, to revoke or vary a declaration under subsection 85(2) in relation to a drug or medicinal preparation.

Where a revocation or variation of a subsection 85(2) declaration would have the result that a drug or medicinal preparation would cease to be a listed drug, the Minister must, under subsection 101(4AAB) of the Act, obtain the advice in writing of PBAC before making the revocation or variation. Under subsection 101(4AAC), this PBAC advice is to be tabled in Parliament with the related declaration under subsection 101(4AAA).

Changes to the PBS effected by this Instrument

The changes made to the PBS by this Instrument are summarised, by subject matter, in Attachment 2.

Additional responsible persons have been determined under subsection 84AF(1) of the Act. The prerequisites to the exercise of this power which are contained in that subsection (and explained in the section above headed 'Minister's powers - responsible persons') have been satisfied.

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.

The Instrument commences on 1 May 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. 5)* and may also be cited as PB 31 of 2011.

Section 2 Commencement

This section provides that the Instrument commences on 1 May 2011.

Section 3 Amendment of PB 108 of 2010

This section provides that Schedule 1 to the Instrument amends PB 108 of 2010.

Schedule 1 Amendments

Schedule 1 sets out the amendments to PB 108 of 2010. These amendments are summarised in Attachment 2.

SUMMARY OF CHANGES

Listed Drug Deleted

Copper Sulfate

Forms Added

Atropine	Injection containing atropine sulfate 600 micrograms in 1 mL
Docetaxel	Solution concentrate for I.V. infusion 160 mg in 16 mL
Interferon Beta-1a	Injection 44 micrograms (12,000,000 I.U.) in 0.5 mL single dose autoinjector
Levodopa with Carbidopa	Intestinal gel containing 20 mg levodopa with 5 mg carbidopa (as monohydrate) per mL, 100 mL

Brands Added

Diazepam	Tablet 2 mg (APO-Diazepam) Tablet 5 mg (APO-Diazepam)
Escitalopram	Tablet 10 mg (as oxalate) (Escicor 10; Pharmacor Escitalopram 10) Tablet 20 mg (as oxalate) (Escicor 20; Pharmacor Escitalopram 20)
Folinic acid	Injection containing calcium folinate equivalent to 300 mg folinic acid in 30 mL (Calcium Folate Ebewe)
Metformin	Tablet containing metformin hydrochloride 500 mg (APO-Metformin 500) Tablet containing metformin hydrochloride 850 mg (APO-Metformin 850)
Pioglitazone	Tablet 15 mg (as hydrochloride) (Vexazone) Tablet 30 mg (as hydrochloride) (Vexazone) Tablet 45 mg (as hydrochloride) (Vexazone)
Risedronic Acid	Tablet containing risedronate sodium 35 mg (Acris Once-a-Week)
Ramipril	Capsule 5 mg (Ramipril-GA)
Terbinafine	Tablet 250 mg (as hydrochloride) (Tinasil)
Valaciclovir	Tablet 500 mg (as hydrochloride) (Valacor 500)
Valaciclovir (s.100)	Tablet 500 mg (as hydrochloride) (Zelitrex)

Brands Deleted

Alprazolam	Tablet 1 mg (Alprazolam-GA) Tablet 2 mg (Alprazolam-GA)
Aspirin	Tablet 100 mg (DBL Aspirin 100 mg)
Lisinopril	Tablet 10 mg (Lisinopril Hexal)

Alteration of Maximum Quantity

Listed Drug	Form	Alteration	
		From:	To:
Morphine	Capsule containing morphine sulfate 30 mg (controlled release)	10	14

Capsule containing morphine sulfate 60 mg (controlled release)	10	14
Capsule containing morphine sulfate 90 mg (controlled release)	10	14
Capsule containing morphine sulfate 120 mg (controlled release)	10	14
Tablet containing morphine sulfate 5 mg (controlled release)	20	28
Tablet containing morphine sulfate 10 mg (controlled release)	20	28
Tablet containing morphine sulfate 15 mg (controlled release)	20	28
Tablet containing morphine sulfate 30 mg (controlled release)	20	28
Tablet containing morphine sulfate 60 mg (controlled release)	20	28
Tablet containing morphine sulfate 100 mg (controlled release)	20	28
Tablet containing morphine sulfate 200 mg (controlled release)	20	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate 20 mg per sachet	20	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate 30 mg per sachet	20	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate 60 mg per sachet	20	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate 100 mg per sachet	20	28
Sachet containing controlled release granules for oral suspension, containing morphine sulfate 200 mg per sachet	20	28

Alteration of Brand and Responsible Person

Listed Drug	Form	Brand	Alteration
Fluoxetine	Capsule 20 mg (as hydrochloride)	<i>From:</i> Fluoxebell	<i>From:</i> Bellwether Pharma Ltd (BF)
		<i>To:</i> Fluoxetine RBX	<i>To:</i> Ranbaxy Australia Pty Limited (RA)

Alteration of Authorised Prescriber

Listed Drug	Form	Alteration
Pancreatic Extract	Granules (enteric coated) providing not less than 5,000 BP units of lipase activity per 100 mg, 20 g <i>[Max Quantity 3 and Number of Repeats 10]</i>	Allowance to prescribe extended to authorised Nurse Practitioners

Alteration of Responsible Person Code

This alteration affects the responsible person code only – the responsible person for this item has not changed

Listed Drug	Form	Brand	Alteration
Mefenamic Acid	Capsule 250 mg	Ponstan	<i>From:</i> PD <i>To:</i> PF

Alteration of Responsible Person

FK *From:* PharmaLink Pty Ltd *To:* Invida Australia Pty Ltd

Responsible Person Code Deleted from Schedule 3

GY [Mayne Pharma International Pty Ltd]

PD [Pfizer Australia Pty Ltd]