EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 87 OF 2008

NATIONAL HEALTH ACT 1953

AMENDMENT DETERMINATIONS UNDER SECTIONS 85, 85A and 88

Purpose and operation

Part VII of the *National Health Act 1953* (the Act) is the legislative basis of the Pharmaceutical Benefits Scheme (PBS) by which the Commonwealth provides reliable, timely, and affordable access to a wide range of medicines for all Australians.

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

Drugs and medicinal preparations to which Part VII applies are declared by the Minister by legislative instrument to be so under subsection 85(2). These are listed drugs as defined in subsection 84(1). Part VII also applies to certain extemporaneously-prepared medicinal preparations as a result of declarations under paragraph 85(2)(b).

Subsection 85(3) authorises the Minister by legislative instrument to determine by reference to strength, type of unit, size of unit, or otherwise, the form or forms of a listed drug.

Subsection 85(5) authorises the Minister by legislative instrument to determine the manner of administration of a form of a listed drug where the form has been determined under subsection 85(3).

Subsection 85(6) authorises the Minister by legislative instrument to determine a brand of a pharmaceutical item. A "brand" is defined in subsection 84(1) to mean the trade name which the person who is or will be the "responsible person" supplies the pharmaceutical item, or if there is no trade name, the name of the responsible person. The responsible person for a brand of a pharmaceutical item is determined by the Minister by legislative instrument under section 84AF.

Subsection 85A(2) authorises the Minister to determine various matters with respect to the writing of prescriptions by persons included in a specified class of persons for the supply of a pharmaceutical benefit. Paragraph 85A(2)(a) authorises the determination of the maximum quantity or number of units that may in one prescription be directed to be supplied for all purposes or for a particular purpose. Paragraph 85A(2)(b) authorises the determination of the maximum number of occasions in which the supply may in one prescription be directed to be repeated for all purposes or a particular purpose. Paragraph 85A(2)(c) authorises the determination of the manner of administration that may in a prescription be directed to be used.

Section 88 provides for various matters relating to the prescribing of pharmaceutical benefits. Subsection 88(1A) authorises the Minister to determine the pharmaceutical benefits for the supply of which a dental practitioner is authorised to write a prescription.

This instrument determines matters under subsections 85(3), 85(5), 85(6), 85A(2), and 88(1A).

This legislative instrument in giving effect to recommendations of the Pharmaceutical Benefits Advisory Committee (PBAC) amends determinations under sections 85, 85A and 88 made by legislative instrument number PB 75 of 2008 which came into effect on 1 August 2008. The amendments are set out in the items of Schedule 1 to the instrument.

A provision-by-provision description of the instrument is contained in the Attachment.

This instrument, expressed to commence on 1 September 2008, was made on 1 August 2008.

Consultations

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 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 the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC. When recommending the listing of a medicine on the PBS, the 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.

ATTACHMENT

Paragraph 1: provides that this instrument commences on 1 September 2008.

Paragraph 2: provides that Schedule 1 amends PB 75 of 2008.

Schedule 1: provides for the following amendments:

SCHEDULE 1 – PART 1

Forms Added

Clarithromycin	Powder for oral liquid 250 mg per mL, 50 mL
Glucose Indicator—Blood	Electrode strips, 25 (On-Call Plus)

Brands Added

Alendronic Acid	Tablet 70 mg (as alendronate sodium) (Alendronate Sandoz)
Bicalutamide	Tablet 50 mg (Bicalutamide Ranbaxy)
Cephalexin	Capsule 250 mg (anhydrous) (Cephatrust 250)
	Capsule 500 mg (anhydrous) (Cephatrust 500)
Lisinopril	Tablet 5 mg (Lisinotrust 5)
	Tablet 10 mg (Lisinotrust 10)
	Tablet 20 mg (Lisinotrust 20)
Metformin	Tablet containing metformin hydrochloride 500 mg (Metformin generichealth)
	Tablet containing metformin hydrochloride 850 mg (Metformin generichealth)
Omeprazole	Tablet 20 mg (Omeprazole Ranbaxy)
Paracetamol	Tablet 500 mg (Pharmacy Choice Paracetamol)
Quinapril	Tablet 500 mg (as hydrochloride) (Quinapril Sandoz)
Ramipril	Capsule 1.25 mg (Pharmacor Ramipril 1.25)
	Capsule 2.5 mg (Pharmacor Ramipril 2.5)
	Capsule 5 mg (Pharmacor Ramipril 5)
	Capsule 10 mg (Pharmacor Ramipril 10)
	Tablet 10 mg (Ramipril Sandoz)
Sertraline	Tablet 50 mg (as hydrochloride) (Sertratrust 50)
	Tablet 100 mg (as hydrochloride) (Sertratrust 100)
Simvastatin	Tablet 10 mg (Simvatrust 10)
	Tablet 20 mg (Simvatrust 20)
	Tablet 40 mg (Simvatrust 40)
	Tablet 80 mg (Simvatrust 80)
Trandolapril	Capsule 500 micrograms (APO-Trandolapril; Trandolapril-DP)
	Capsule 1 mg (APO-Trandolapril; Trandolapril-DP)
	Capsule 2 mg (APO-Trandolapril; Trandolapril-DP)
	Capsule 4 mg (APO-Trandolapril; Trandolapril-DP)

Listed Drug Deleted

Dipivefrine	Eye drops containing dipivefrine hydrochloride 1 mg per mL, 10 mL

Brands Deleted

Diazepam	Tablet 2 mg (Ranzepam)
Electrolyte Replacement, Oral	Oral rehydration salts containing glucose 3.56 g, sodium chloride 470 mg, potassium chloride 300 mg and sodium acid citrate 530 mg per sachet, 10 (Chem mart Oral Rehydration Salts; Terry White Chemists Oral Rehydration Salts)
Tramadol	Injection containing tramadol hydrochloride 100 mg in 2 mL (Tramahexal)

SCHEDULE 1 – PART 2

Brands Added

Omeprazole	Tablet 20 mg (Omeprazole Ranbaxy)
Paracetamol	Tablet 500 mg (Pharmacy Choice Paracetamol)

Brand Deleted

Diazepam	Tablet 2 mg (Ranzepam)

SCHEDULE 2 – PART 1

Brand Deleted

Diazepam	Tablet 2 mg (Ranzepam)

SCHEDULE 3 – PART 1

Brands Added

Cephalexin	Capsule 250 mg (anhydrous) (Cephatrust 250)
	Capsule 500 mg (anhydrous) (Cephatrust 500)
Paracetamol	Tablet 500 mg (Pharmacy Choice Paracetamol)

Brand Deleted

Diazepam	Tablet 2 mg (Ranzepam)
Tramadol	Injection containing tramadol hydrochloride 100 mg in 2 mL (Tramahexal)

SCHEDULE 3 – PART 2

Brand Added

Paracetamol	Tablet 500 mg (Pharmacy Choice Paracetamol)