EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 15 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 tradename, 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 89 of 2007 which came into effect on 1 December 2007. 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 February 2008, was made on 2 January 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 February 2008.

Paragraph 2: provides that Schedule 1 amends PB 89 of 2007.

Schedule 1: provides for the following amendments:

SCHEDULE 1 – PART 1

Brands Added

Fosinopril	Tablet containing fosinopril sodium 10 mg (Fosinopril Winthrop)
	Tablet containing fosinopril sodium 20 mg (Fosinopril Winthrop)
Fosinopril with Hydrochlorothiazide	Tablet containing fosinopril sodium 10 mg with hydrochlorothiazide 12.5 mg (Fosinopril/HCT Winthrop 10 mg/12.5 mg)
	Tablet containing fosinopril sodium 20 mg with hydrochlorothiazide 12.5 mg (Fosinopril/HCT Winthrop 20 mg/12.5 mg)
Gabapentin	Tablet 600mg (GenRx Gabapentin)
	Tablet 800 mg (GenRx Gabapentin)
Omeprazole	Tablet 20 mg (GenRx Omeprazole)
Oxybutynin	Tablet containing oxybutynin hydrochloride 5 mg (Oxybutynin Winthrop)
Quinapril	Tablet 5 mg (as hydrochloride) (APO-Quinapril, Pharmacor Quinapril 5, Quinapril-DP)
	Tablet 10 mg (as hydrochloride) (APO-Quinapril, Pharmacor Quinapril 10, Quinapril-DP)
	Tablet 20 mg (as hydrochloride) (APO-Quinapril, Pharmacor Quinapril 20, Quinapril-DP)
Sumatriptan	Tablet 50 mg (as succinate) (Sumagran 50)

Brands Deleted

Influenza Vaccine	Injection containing inactivated, split virion influenza vaccine, 0.5 mL of which contains antigens representative of the following types: A/New Caledonia/20/99 (H_1N_1)-like strain 15 micrograms haemagglutinin; A/Wisconsin/67/2005 (H_3N_2)-like strain 15 micrograms haemagglutinin; B/Malaysia/2506/2004-like strain 15 micrograms haemagglutinin; 0.5 mL pre-filled syringe (Fluarix)

Isotretinoin	Capsule 20 mg (Isohexal)
Trimethoprim with Sulfamethoxazole	Tablet 80 mg-400 mg (Septrin)

Alteration of Listed Drug and Form

From: Metoprolol	Pack containing 15 tablets metoprolol succinate 23.75 mg (controlled release), 15 tablets metoprolol succinate 47.5 mg (controlled release) and 15 tablets metoprolol succinate 95 mg (controlled release)
To: Metoprolol succinate	Pack containing 15 tablets 23.75 mg (controlled release), 15 tablets 47.5 mg (controlled release) and 15 tablets 95 mg (controlled release)
From: Metoprolol	Tablet containing metoprolol succinate 190 mg (controlled release)
To: Metoprolol succinate	Tablet 190 mg (controlled release)
From: Metoprolol	Tablet containing metoprolol succinate 23.75 mg (controlled release)
To: Metoprolol succinate	Tablet 23.75 mg (controlled release)
From: Metoprolol	Tablet containing metoprolol succinate 47.5 mg (controlled release)
To: Metoprolol succinate	Tablet 47.5 mg (controlled release)
From: Metoprolol	Tablet containing metoprolol succinate 95 mg (controlled release)
To: Metoprolol succinate	Tablet 95 mg (controlled release)

Alteration of Form

Influenza Vaccine

Alteration of Maximum Quantity

Cetuximab [Solution for I.V. infusion 100 mg in 50 mL]

From: 6

To: 1

Alteration of Brand

Cephalexin [Capsule 250 mg (anhydrous), Capsule 500 mg (anhydrous)]

From: Cephalexin-Lupin

To: Cephalexin Max

SCHEDULE 1 - PART 2

Brand Added

Omeprazole	Tablet 20 mg (GenRx Omeprazole)

Alteration of Maximum Quantity

Cetuximab [Solution for I.V. infusion 100 mg in 50 mL]

From: 4

To: 1

Alteration of Purposes

Pemetrexed

SCHEDULE 3 – PART 1

Brand Deleted

Trimethoprim with Sulfamethoxazole	Tablet 80 mg-400 mg (Septrin)

Alteration of Brand

Cephalexin [Capsule 250 mg (anhydrous), Capsule 500 mg (anhydrous)]

From: Cephalexin-Lupin

To: Cephalexin Max