

EXPLANATORY STATEMENT

NATIONAL HEALTH (PHARMACEUTICAL BENEFITS – EARLY SUPPLY) AMENDMENT SEPTEMBER 2009 - SPECIFICATION UNDER SUBSECTION 84AAA(2)

INSTRUMENT NUMBER PB 84 OF 2009

NATIONAL HEALTH ACT 1953

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).

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.

These determinations govern what constitutes a pharmaceutical benefit (defined in subsection 84(1)) under part VII of the Act.

Paragraph 85A(2)(a) authorises the Minister to determine 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 Minister to determine the maximum number of occasions on which the supply may, in one prescription, be directed to be repeated for all purposes or a particular purpose.

Paragraph 84C(4A)(a) of the Act refers to repatriation pharmaceutical benefits supplied under the scheme established under section 91 of the Veterans' Entitlements Act 1986 or supplied in accordance with a determination made under paragraph 256(1)(c) of the Military Rehabilitation and Compensation Act 2004.

Subsection 84AAA(1) of the Act provides that a supply of a pharmaceutical benefit to a person (whether or not that supply is a supply of a kind described in paragraph 84C(4A)(a)) is an early supply of a specified pharmaceutical benefit if:

- The supply is made within 20 days after the day of a previous supply of the same pharmaceutical benefit to the person (whether or not the previous supply is a supply of a kind described in paragraph 84C(4A)(a));
- The pharmaceutical benefit is specified in an instrument under subsection 84AAA(2); and
- The supply does not result from a prescription originating from a hospital or a day hospital facility.

The early supply of a specified pharmaceutical benefit includes a supply of a pharmaceutical benefit specified in the instrument, as either a pharmaceutical benefit or a repatriation pharmaceutical benefit within 20 days of a previous supply of the same pharmaceutical benefit (as either a pharmaceutical benefit or a repatriation pharmaceutical benefit) to the same person. The repatriation pharmaceutical benefits supplied under the Repatriation Pharmaceutical Benefits Scheme (RPBS) which are subject to the provisions for early supply of a specified pharmaceutical benefit are those where the repatriation pharmaceutical benefit is the same as a specified pharmaceutical benefit for supply under the PBS.

‘Hospital’ is defined in the subsection 3(1) of the *Health Insurance Act 1973* to mean a recognised hospital, a private hospital, or a hospital that is declared by the Minister to be a hospital for the purposes of that definition. ‘Day hospital facility’ is defined in subsection 4(1) of the *National Health Act 1953*.

Subsections 84C(4) and 84C(4A) of the Act regulate the supply or repeated supply of pharmaceutical benefits and repatriation pharmaceutical benefits which are taken into account in totalling amounts charged for the purpose of demonstrating eligibility for a safety net concession card or safety net entitlement card.

Subsection 84C(4AA) of the Act provides that the amount charged for an early supply of a specified pharmaceutical benefit must not be taken into account when determining eligibility for a concession card or entitlement card, if the supply is an early supply of a pharmaceutical benefit specified in the instrument and the supply is not a supply of an out-patient medication. *Out-patient medication* is defined in subsection 84(1) of the Act to mean a drug or medicinal preparation supplied through the out-patient department of a public hospital.

Subsection 87(2) of the Act sets out the amounts to be charged to patients for the supply of pharmaceutical benefits. These provisions form the basis for the patient charges which apply for general benefit prescriptions (currently up to \$32.90), concessional benefit prescriptions (currently \$5.30), concession card prescriptions (currently \$5.30), and entitlement prescriptions (free). The provisions also set the charges for prescriptions which are an early supply of a pharmaceutical benefit. Prescriptions for repatriation pharmaceutical benefits are treated as for concessional benefit prescriptions and entitlement prescriptions.

Section 99 of the Act regulates the amounts that pharmacists and medical practitioners who are approved under the Act to supply pharmaceutical benefits, are entitled to be paid by the Commonwealth for supplying those benefits. This includes the amount to be paid for prescriptions which are an early supply of a pharmaceutical benefit.

This legislative instrument is made under subsection 84AAA(2) of the Act. Subsection 84AAA(2) of the Act provides that the Minister may specify, by legislative instrument, pharmaceutical benefits for the purposes of paragraph 84AAA(1)(b) of the Act. Subsection 84AAA(3) provides that the instrument may specify a pharmaceutical item by reference to the circumstances in which a pharmaceutical benefit that has the pharmaceutical item is supplied or any other circumstances in relation to a pharmaceutical benefit that has the pharmaceutical item.

The pharmaceutical items specified in the Instrument are specified by the Minister who can take into account the advice of the Pharmaceutical Benefits Advisory Committee (PBAC). The PBAC is the 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 selected 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.

Section 101 of the Act sets out the functions of the PBAC in relation to making recommendations and providing advice to the Minister regarding the medicines to be declared as pharmaceutical benefits under Part VII of the Act, and any other matter concerning Part VII of the Act referred to the PBAC by the Minister.

Subsection 101(3AA) requires the PBAC to make recommendations to the Minister about what should be specified in an instrument made under 84AAA(2).

This Instrument was made on 14 August 2009 and commences on 1 September 2009.

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

Details of the Instrument are set out in Attachment 1.

Effect of the Instrument

This Instrument amends the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 - Specification Under Subsection 84AAA(2)*, PB No. 30 of 2009. The Instrument amends the list of items specified under subsection 84AAA(2). Details of the changes effective from 1 September 2009 are set out in Attachment 2. The additional pharmaceutical item is described in Table 1. The deleted pharmaceutical item is described in Table 2.

Consultations

Consultation regarding implementation of the arrangements for early supply of specified pharmaceutical benefits occurred with Medicare Australia, the Department of Veterans' Affairs, the Medical Software Industry Association (MSIA), and peak pharmacy organisations (including the Pharmacy Guild of Australia, the Pharmaceutical Society of Australia, the Australian Association of Consultant Pharmacy, and the Society of Hospital Pharmacists of Australia). The PBAC has provided advice on which pharmaceutical benefits should be specified in the Instrument.

ATTACHMENT 1

Section 1: provides that the name of the Instrument is the *National Health (Pharmaceutical Benefits – Early Supply) Amendment September 2009 - specification under subsection 84AAA(2)* and that the Instrument may also be cited as No. PB 84 of 2009.

Section 2: provides that the Instrument commences on 1 September 2009.

Section 3: provides that this Amendment amends the *National Health (Pharmaceutical Benefits – Early Supply) Instrument 2009 - specification under subsection 84AAA(2)*, No. PB 30 of 2009.

Schedule 1: specifies the pharmaceutical items in the pharmaceutical benefits for the purposes of paragraph 84AAA(1)(b) of the Act by reference to the drug or medicinal product as declared under subsection 85(2), the form (strength, type, size, etc.) as determined under subsection 85(3), manner of administration as determined under subsection 85(5), maximum quantity or number of units as determined under paragraph 85A(2)(a); maximum repeats as determined under paragraph 85A(2)(b), and any other circumstances that apply under paragraph 84AAA(3)(b) of the Act.

ATTACHMENT 2

Table 1. Form added

Lansoprazole	Tablet 30 mg (orally disintegrating)
--------------	--------------------------------------

Table 2. Form deleted

Etanercept	Injection set containing 4 vials powder for injection 50 mg and 4 pre-filled syringes solvent 1 mL
------------	--