EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

DECLARATION UNDER SUBSECTION 85(2)

No. PB 32 OF 2007

Purpose and operation

1. The purpose of the Australian Pharmaceutical Benefits Scheme (PBS) is to provide timely, reliable and affordable access for the Australian community to necessary and cost-effective medicines.

2. The PBS is regulated by Part VII of the *National Health Act 1953* (the Act), which provides for the supply of listed drugs and medicinal preparations as pharmaceutical benefits.

3. "Pharmaceutical benefit" is defined under subsection 84(1) of the Act as a drug or medicinal preparation in relation to which, by virtue of section 85 of the Act, Part VII of the Act applies.

4. Subsection 85(2) of the Act provides that, subject to subsection 85(3) of the Act, the drugs and medicinal preparations to which Part VII of the Act applies are:

   (a) drugs and medicinal preparations that are:

      (i) declared by the Minister, in writing, to be drugs and medicinal preparations to which Part VII applies; or

      (ii) included in a class of drugs and medicinal preparations declared by the Minister, in writing, to be a class of drugs and medicinal preparations to which Part VII applies; and

   (b) medicinal preparations composed of:

      (i) one or more of the drugs and medicinal preparations referred to in paragraph (a), being a drug or medicinal preparation that is, or drugs or medicinal preparations that are, included in a class of drugs and medicinal preparations declared by the Minister, in writing, to be a class of drugs and medicinal preparations to which this paragraph applies; and

      (ii) one or more additives as are declared by the Minister, in writing, to be additives to which this paragraph applies.

5. Subsection 85(2A) of the Act provides that the Minister may, in a declaration under subsection 85(2) of the Act:

   (a) declare that a particular pharmaceutical benefit is a relevant pharmaceutical benefit for the purposes of section 88A of the Act; and

   (b) specify the circumstances in which the writing of a prescription for the supply of the pharmaceutical benefit is to be authorised under Part VII of the Act.

6. Section 88A of the Act provides that where a pharmaceutical benefit is declared, in a declaration made under subsection 85(2) of the Act, to be a relevant pharmaceutical benefit for the purposes of that section, the writing of a prescription for the supply of the benefit is authorised under Part VII of the Act only in the circumstances specified in the declaration pursuant to subsection 85(2A) of the Act.

7. The declaration made under subsection 85(2) of the Act sets out the drugs and medicinal preparations to which Part VII of the Act applies and the restrictions, if any, that apply to the prescribing of such drugs and medicinal preparations as pharmaceutical benefits.

8. The declaration made under subsection 85(2) of the Act on 12 March 2007 with effect from 1 April 2007 (No. PB 21 of 2007) is repealed and substituted with this declaration.

9. This declaration is remade to give effect, as from 1 May 2007, to changes to the list of drugs and medicinal preparations available as pharmaceutical benefits, as recommended by the Pharmaceutical Benefits Advisory Committee. Changes to Schedules 1 and 3 of the declaration are detailed in the attached summary of changes.

Consultations

10. The Pharmaceutical Benefits Advisory Committee (PBAC) is the independent expert body, established by section 100A of the Act, that makes recommendations to the Minister for Health and Ageing about which drugs and medicinal preparations should be available as pharmaceutical benefits. Under subsection 101(4) of the Act, a drug or medicinal preparation may not be declared to be a drug or medicinal preparation to which Part VII of the Act applies unless the PBAC has recommended that it be so declared. When recommending a medicine be listed 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.

11. The declaration gives effect to recommendations made by the PBAC. 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.

12. Details of the declaration are set out in the Attachment.

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

14. The declaration was made on 30 March 2007 and came into operation on 1 May 2007.

SUMMARY OF CHANGES

SCHEDULE 1

Additions

Hydroxocobalamin Acetate

Perindopril Arginine with Indapamide Hemihydrate

Trandolapril with Verapamil Hydrochloride

"XLYS, LOW TRY Analog"

"XLYS, LOW TRY Maxamaid"

Alteration of Circumstances

Etanercept [extension of PBS availability of 50 mg injection to include all circumstances for which 25 mg injection is available]

Glucose Indicator - Blood [addition of electrode strips, 50 (Accu-Chek Performa) and reagent strips, 50 (Betacheck G5)]

Sodium Cromoglycate [deletion of solution for inhalation 20 mg in 2mL ampoule]

SCHEDULE 3

Additions

Perindopril Arginine with Indapamide Hemihydrate

Trandolapril with Verapamil Hydrochloride

Verapamil Hydrochloride

ATTACHMENT

Paragraph 1 provides that this declaration commences on 1 May 2007.

Paragraph 2 provides that the declaration under subsection 85(2) of the *National Health Act 1953* (the Act) made on 12 March 2007 (No. PB 21 of 2007) is repealed.

Paragraph 3 defines the following terms for the purposes of the declaration:

- "Act"
- "base-priced drug";
- "electronic communication";
- "extemporaneously-prepared pharmaceutical benefit";
- "Medicare Australia CEO";
- "palliative care patient";
- "PBS";
- "ready-prepared pharmaceutical benefit"; and
- "Regulations".

Paragraph 4 provides that the drugs and medicinal preparations listed in column 1 of Schedules 1 or 1A are pharmaceutical benefits if prescribed by a medical practitioner in specified circumstances.

Paragraph 4A provides that the drugs and medicinal preparations listed in column 1 of Schedule 2 are pharmaceutical benefits if prescribed by a participating dental practitioner in specified circumstances.

Paragraph 5 provides that a compounded medicinal preparation is a pharmaceutical benefit only where that compound consists of:

- two or more of the pharmaceutical benefits listed in column 1 of Schedule 3; or
- one or more of the pharmaceutical benefits listed in column 1 of Schedule 3 and that the name of that compound is specified in Schedule 4, in which case paragraphs 7 and 8 of this declaration apply.

Paragraph 6 provides that a compound consisting of a ready-prepared pharmaceutical benefit is not a pharmaceutical benefit, unless that ready-prepared pharmaceutical benefit is compounded with a pharmaceutical benefit specified in column 1 of Schedule 3.

Paragraph 7 provides that a compound consisting of one or more of the drugs or medicinal preparations specified in Schedule 4 is a pharmaceutical benefit.

Paragraph 8 provides that a compound consisting of one or more drugs or medicinal preparations specified in Schedule 4, together with one or more substances listed in Schedule 5, is a pharmaceutical benefit.

Paragraph 9 provides that the substances listed in Schedule 5 may be used as additives in compounds which are pharmaceutical benefits.

Paragraph 10 provides that Part VII of the *National Health Act 1953* applies to the drugs and medicinal preparations listed in Schedule 6 of this declaration.

Paragraph 11 provides that the drugs and medicinal preparations listed in Schedule 6 of this declaration are additional pharmaceutical benefits made available under section 100 of the *National Health Act 1953*.

Paragraph 12 provides that a drug or medicinal preparation specified in column 1 of Schedules 1, 1A, 2 or 4 is only a pharmaceutical benefit when prescribed for the circumstances specified in column 2 of those Schedules.

Paragraph 13 provides that the circumstances that apply to those pharmaceutical benefits listed in column 1 of Schedule 4 also apply to any compounds containing any of those substances.

Paragraph 14 provides that:

a. where a class of persons is specified in column 2 of Schedules 1, 1A, 2 or 4, the pharmaceutical benefit is to be supplied to a person included in that class of persons;

b. where a disease or condition is specified in column 2 of Schedules 1, 1A, 2 or 4:

   (i) if subparagraph (ii) does not apply, the pharmaceutical benefit is to be supplied for the treatment of that disease or condition; or

   (ii) if a class of persons is also specified in those circumstances, the pharmaceutical benefit is to be supplied for the treatment of that disease or condition in a person included in that class of persons;

c. where a purpose is specified in column 2 of Schedules 1, 1A, 2 or 4, the pharmaceutical benefit is to be supplied for that purpose;

d. where column 2 of Schedules 1, 1A, 2 and 4 specifies that compliance with authority procedures (set out in subparagraph 14(d)) is required, then the medical practitioner must submit the prescription for supply of the pharmaceutical benefit by:

   (i) preparing and signing the prescription:

      (A) in a form approved by the Secretary, and completed in ink in the medical practitioner's handwriting; or

      (B) in a form approved by the Secretary, by means of a computer; or

      (C) in a form prepared by means of a computer and approved in writing for the purpose by the Secretary and in a format approved in writing by the Secretary; or

      (D) by a method approved by the Secretary in writing.

   (ii) submitting the prescription by telephone, giving the Medicare Australia CEO the details of that prescription which has been prepared and signed in accordance with subsubparagaph (i); or

   (iii) where the medical practitioner is unable to obtain authorisation from the Medicare Australia CEO due to failure of telephone systems, submitting the prescription in line with subsubparagraph (ii) and according to the instructions stipulated in an emergency telephone message from the medical practitioner to the Medicare Australia CEO;

   (iv) by submitting the details of the prescription, which has been prepared and signed by the medical practitioner (in accordance with subsubparagraph (i)) to the Medicare Australia CEO by means of electronic communication (of a kind which has been approved by the Medicare Australia CEO)

Paragraph 14A provides that, if the prescription has been prepared and signed by the medical practitioner in accordance with subsubparagraph 14(d)(i), that prescription may be submitted by one of that medical practitioner's employees.

Paragraph 15 provides that, subject to paragraph 15B, where a prescription is submitted under subparagraph 14(d), authorisation may be made:

a. by the Medicare Australia CEO signing for the authorisation on the prescription and:

   (i) if the Medicare Australia CEO requires that the medical practitioner must alter the prescription, by returning the prescription to the medical practitioner for alteration before the medical practitioner gives it to the patient; or

   (ii) in any other case:

      (A) by returning it to the medical practitioner; or

      (B) by sending it to the person for whom it was prepared; or

b. orally, at the time the Medicare Australia CEO is given details of the prescription, if the prescription was submitted in accordance with subsubparagraph 14(d)(ii); or

c. by the Medicare Australia CEO sending the authorisation to the medical practitioner by electronic communication, if the prescription was submitted in accordance with subsubparagraph 14(d)(iv).

Paragraph 15A provides that, if the Medicare Australia CEO authorises a prescription orally, in accordance with subparagraph 15(b) or (c):

a. the Medicare Australia CEO must tell the medical practitioner, either orally or by electronic communication, the number of the authority prescription; and

b. the medical practitioner must mark the number on the prescription and retain a copy of the prescription for 1 year from the date of authorisation.

Paragraph 15B provides that authorisation is deemed to be granted where a medical practitioner has submitted a prescription in accordance with subsubparagraph 14(d)(iii), and where the prescription has been completed in accordance with the instructions stipulated in the emergency telephone message provided by the Medicare Australia CEO.

Paragraph 16(a) provides that where the words "for use in accordance with paragraph 16" are used in column 2 of Schedule 1, that the pharmaceutical benefit is to be supplied for the treatment, in conjunction with dietary therapy, of a patient identified as being in one of the following very high risk categories:

i. coronary heart disease which has become symptomatic;

ii. cerebrovascular disease which has become symptomatic;

iii. peripheral vascular disease which has become symptomatic;

iv. diabetes mellitus with microalbuminuria (defined as urinary albumin excretion rate of greater than 20 micrograms per minute, or urinary albumin to creatinine ratio of greater than 2.5 for males or greater than 3.5 for females);

v. diabetes mellitus in Aboriginal or Torres Strait Islander patients;

vi. diabetes mellitus in patients aged 60 years or more;

vii. family history of coronary heart disease which has become symptomatic before the age of 55 years in two or more first degree relatives;

viii. family history of coronary heart disease which has become symptomatic before the age of 45 years in one or more first degree relatives; or

Paragraph 16(b) provides that if subparagraph 16(a) does not apply—that the pharmaceutical benefit is to be supplied for the treatment, in conjunction with dietary therapy, of a patient who, after at least 6 weeks of dietary therapy, qualifies to receive the benefit in accordance with the table at paragraph 16(b).

The Schedules

Schedule 1 to the declaration lists those drugs and medicinal preparations that are pharmaceutical benefits when prescribed by a medical practitioner for the circumstances specified (if any).

Schedule 1A to the declaration lists those drugs and medicinal preparations that are pharmaceutical benefits when prescribed by a medical practitioner for the circumstances specified for patients receiving palliative care.

Schedule 2 to the declaration lists those drugs and medicinal preparations that are pharmaceutical benefits when prescribed by a participating dental practitioner for the circumstances specified (if any).

Schedule 3 to the declaration lists allowable compounds of ready-prepared pharmaceutical benefits.

Schedule 4 to the declaration lists those drugs or medicinal preparations that may be used as ingredients of extemporaneously-prepared pharmaceutical benefits.

Schedule 5 to the declaration lists those drugs and medicinal preparations that may be used as additives in compounds that are pharmaceutical benefits.

Schedule 6 to the declaration lists those additional pharmaceutical benefits that are made available under arrangements provided for by section 100 of the *National Health Act 1953*.