EXPLANATORY STATEMENT

INSTRUMENT NUMBER PB 121 OF 2008

NATIONAL HEALTH ACT 1953

SPECIAL ARRANGEMENTS UNDER SUBSECTION 100(1)

CHEMOTHERAPY PHARMACEUTICALS ACCESS PROGRAM

Purpose and operation

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.

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.

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

Subsection 100(1) of the Act provides that the Minister may make special arrangements for providing that an adequate supply of special pharmaceutical products will be available to persons:

a. who are living in isolated areas; or

b. who are receiving medical treatment in such circumstances that pharmaceutical benefits:

   (i) cannot be conveniently or efficiently supplied in accordance with Part VII of the Act; or

   (ii) are inadequate for that medical treatment.

Subsection 100(2) of the Act provides that the Minister may vary or revoke a special arrangement made under subsection 100(1).

Subsection 100(3) provides that Part VII of the Act has effect subject to a special arrangement made under subsection 100(1).

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. Schedule 6 of the declaration under subsection 85(2) lists those drugs and medicinal preparations that may be made available under arrangements provided for by section 100 of the Act.

The Chemotherapy Pharmaceuticals Access Program is a set of Arrangements made under subparagraph 100(b)(i) of the Act for the purpose of the supply of chemotherapy pharmaceuticals at public hospitals to non-admitted patients, day admitted patients and patients on discharge.

Paragraph 2(g) of these Arrangements incorporates by reference Schedule F of the Australian Health Care Agreements. These agreements can be found at the Commonwealth Department of Health and Ageing's internet site (www.health.gov.au).

These Arrangements constitute a legislative instrument for the purposes of the *Legislative Instruments Act 2003*.

A provision-by-provision description of this instrument is contained in Attachment 1.

This instrument (No. PB 121 of 2008) is made under subparagraph 100(b)(i) of the Act and revokes the instrument previously made under subparagraph 100(b)(i) of the Act (No. PB 82 of 2008). The previous instrument was made on 9 July 2008, commenced on 1 August 2008 and was the subject of regular amendments, the last of which commenced on 1 November 2008.

Many of the matters determined under this instrument are the same as under the previous instrument, as amended up to 1 November 2008. The changes made in this instrument to matters determined under subparagraph 100(b)(i) of the Act since the last amendment to the previous instrument, are set out in Attachment 2 to this Explanatory Statement and is titled Summary of Changes.

This instrument, expressed to commence on 1 December 2008, was made on 5 November 2008.

Consultations

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.

The public hospital pharmaceutical reforms provide Australian Government subsidised access to a range of cancer chemotherapy drugs, listed on the PBS, for day admitted and non-admitted public hospital patients within a clinical setting under the Chemotherapy Pharmaceutical Access Program. The pharmaceutical reforms are implemented by means of an agreement between the Australian Government and participating States through the Australian Health Care Agreements. To date, Victoria, Western Australia and Queensland are participating in the reforms.

ATTACHMENT

Paragraph 1(a) provides that these Arrangements commence on 1 December 2008.

Paragraph 1(b) provides that instrument No. PB 82 of 2008 is repealed.

Paragraph 2 provides that a word or phrase used in these Arrangements will be taken to have the same meaning as in the *National Health Act 1953* (the Act), the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations) or a declaration, determination or other instrument made under Part VII of the Act or under the Regulations, unless the contrary intention appears. Paragraph 2 also defines certain terms used in these Arrangements.

Paragraph 2(g) of the Chemotherapy Pharmaceutical Access Program Arrangements incorporates by reference Schedule F of the Australian Health Care Agreements. These agreements can be found at the Commonwealth Department of Health and Ageing's internet site (www.health.gov.au).

Paragraph 3 provides that the provisions of the Act, the Regulations, declarations, determinations and other instruments made under the Act shall apply to the prescribing of chemotherapy pharmaceuticals under these Arrangements, except where otherwise specified in these Arrangements.

Paragraph 4 provides that a person is entitled to receive chemotherapy pharmaceuticals under these Arrangements, without payment or other consideration other than the charges specified in paragraphs 20 and 20A, if that person is an eligible person within the meaning of the *Health Insurance Act 1973*, and if that person is receiving treatment as a non-admitted patient, a day admitted patient or a patient on discharge, of a public hospital by a medical practitioner who is affiliated with that hospital.

Paragraph 5 provides that the chemotherapy pharmaceuticals to which these Arrangements apply are listed in column 1 of Schedule 1.

Paragraph 6 provides that the prescribing of a chemotherapy pharmaceutical under these Arrangements is authorised only in the circumstances specified in column 2 of Schedule 1 for that chemotherapy pharmaceutical.

Paragraph 7 provides that:

a. where a class of persons is specified in column 2 of Schedule 1, the chemotherapy pharmaceutical is to be supplied to a person included in that class of persons; or

b. where a disease or condition is specified in column 2 of Schedule 1:
   (i) if subparagraph (ii) does not apply, the chemotherapy pharmaceutical is to be supplied for the treatment of that disease or condition; or
   (ii) if a disease or condition is specified in relation to a class of persons the chemotherapy pharmaceutical is to be supplied for the treatment of that disease or condition in a person included in that class of persons; or

c. where a purpose is specified in column 2 of Schedule 1, the chemotherapy pharmaceutical is to be supplied for that purpose.

Paragraph 8 provides that where a form of a special pharmaceutical product is specified in column 2 of Schedule 2 or Schedule 3, each specified form is a chemotherapy pharmaceutical and these Arrangements do not apply to that chemotherapy pharmaceutical in any other form.

Paragraph 9 provides that a chemotherapy pharmaceutical may only be administered in the manner specified in column 3 of Schedule 2 or column 4 of Schedule 3.

Paragraph 10 provides that the maximum quantity of a chemotherapy pharmaceutical that may be directed to be supplied in one prescription is:

a. for a chemotherapy pharmaceutical listed in column 1 of Schedule 2, the quantity or number, if any, specified in column 4 of that Schedule; or

b. for a chemotherapy pharmaceutical listed in column 1 of Schedule 3, which has been prescribed according to the purposes specified in column 3 of that Schedule, the quantity or number, if any, specified in column 5 of that Schedule.

Paragraph 11 provides that the maximum number of occasions on which a chemotherapy pharmaceutical may be directed to be supplied in one prescription is:

a. for a chemotherapy pharmaceutical listed in column 1 of Schedule 2, the number, if any, specified in column 5 of that Schedule; or

b. for a chemotherapy pharmaceutical listed in column 1 of Schedule 3 which has been prescribed according to the purposes specified in column 3 of that Schedule, the number, if any, specified in column 6 of that Schedule.

Paragraph 12 provides that a chemotherapy pharmaceutical may only be supplied as a brand specified in column 6 of Schedule 2 or column 7 of Schedule 3, and that no other brand may be supplied under these Arrangements.

Paragraph 13 provides that a medical practitioner may prepare a prescription for a chemotherapy pharmaceutical on a medication chart, even though this method of preparing a prescription does not comply with paragraphs 19(1)(a) and (b) of the Regulations, provided that:

a. the medication chart bears the number issued by the Medicare Australia CEO, in pursuance of the function granted to him or her by subsection 18(a) of the *Medicare Australia (Functions of Chief Executive Officer) Direction 2005* made under paragraph 5(1)(d) of the *Medicare Australia Act 1973*, to the medical practitioner who is prescribing the chemotherapy pharmaceutical; and

b. a direction on the medication chart to repeat the supply of the chemotherapy pharmaceutical under paragraph 85A(2)(b) of the Act and subparagraph 19(1)(f)(ii) of the Regulations will be invalid; and

c. a direction on the medication chart to supply an increased quantity of the chemotherapy pharmaceutical under subsection 88(6) of the Act and regulation 24 of the Regulations is taken to be a direction to supply only the maximum quantity for the chemotherapy pharmaceutical that is specified in Schedule 2 or Schedule 3 to these Arrangements; and

d. a direction on the medication chart for the supply of a quantity which is greater than the maximum quantity specified, in column 4 of Schedule 2 or column 5 of Schedule 3, is authorised in accordance with paragraph 15; and

e. where a direction on the medication chart for the supply of a chemotherapy pharmaceutical requires an authorisation from the Medicare Australia CEO, as specified in column 2 of Schedule 1 or column 3 of Schedule 3, an authorisation has been obtained for that supply.

Paragraph 14 provides that a medical practitioner who wishes to prescribe a chemotherapy pharmaceutical, which requires an authorisation under subparagraph 13(e), may seek that authorisation in accordance with subparagraph 14(d) of the declaration in force under subsection 85(2) of the Act, or by arranging authorisation to be sought by the approved hospital authority on behalf of the medical practitioner in accordance with paragraph 16.

Paragraph 15 provides that a medical practitioner who wishes to prescribe a quantity of a chemotherapy pharmaceutical, which requires an authorisation under subparagraph 13(d), may seek that authorisation in accordance with regulation 13 of the Regulations, or by arranging authorisation to be sought by the approved hospital authority on behalf of the medical practitioner in accordance with paragraph 16.

Paragraph 16 provides that, where a medical practitioner arranges for authorisation to be sought by an approved hospital authority for the supply of a chemotherapy pharmaceutical, a pharmacist of that hospital must submit details of the medication chart, which has been prepared and signed by the medical practitioner, by means of computer message to the Medicare Australia authority notification computer system.

Paragraph 17 provides that where a hospital pharmacist submits details of the medication chart to the Medicare Australia authority notifications computer system in order to seek authorisation for the supply of a chemotherapy pharmaceutical on behalf of the medical practitioner in accordance with paragraph 16, and the computer message is received by the Medicare Australia authority notification computer system, the Medicare Australia authority notification computer system may return a message to the approved hospital authority and:

a. if the message indicates approval of the authorisation, the hospital pharmacist must complete the medication chart in accordance with the instructions contained in the message; or

b. if the message indicates that the authorisation has not been approved, or the Medicare Australia computer system fails to return a message, the medical practitioner may resubmit the medication chart details in accordance with subparagraph 14(d) of the declaration in force under subsection 85(2) of the Act or regulation 13 of the Regulations.

Paragraph 18 provides that if the Medicare Australia authority notification computer system returns a message to the approved hospital authority indicating that the authorisation is approved, then the supply of the chemotherapy pharmaceutical is approved under these Arrangements.

Paragraph 19 provides that the approved hospital authority will supply chemotherapy pharmaceuticals to hospital patients as if the medication charts were original prescriptions, provided that:

a. where the medication chart directs to supply more than one chemotherapy pharmaceutical, the approved hospital authority must not defer (pursuant to regulation 26A of the Regulations) the supply of one or more of the chemotherapy pharmaceuticals; and

b. a person authorised by the approved hospital to do so, certifies on the medication chart that the chemotherapy pharmaceutical has been supplied, the date on which it was supplied and signs his/her name (in lieu of the requirements of regulation 31 of the Regulations).

Paragraph 20 provides that an approved hospital authority may charge the person to whom a chemotherapy pharmaceutical has been supplied an amount equal to that which may be charged under subsection 87(2) of the Act for the supply of a pharmaceutical benefit.

Paragraph 20A provides that, in addition to the amount charged under paragraph 20, an approved hospital authority which supplies a chemotherapy pharmaceutical which is :

i. specified in column 1 of Schedule 4; and

ii. in the form specified in column 2 of Schedule 4; and

iii. marketed under the brand specified in column 3 of Schedule 4; and

iv. in the quantity specified in column 4 of Schedule 4;

may charge the person, to whom the chemotherapy pharmaceutical is supplied, the amount calculated by subtracting the amount specified in column 5 of Schedule 4 from the amount specified in column 6 of Schedule 4 for that chemotherapy pharmaceutical.

Paragraph 21 provides that an approved hospital authority that has supplied a chemotherapy pharmaceutical is entitled to be paid by the Commonwealth the amount by which the dispensed price exceeds the amount that the approved hospital authority was entitled to charge under paragraph 20.

Paragraph 22 provides that the dispensed price for the supply of a chemotherapy pharmaceutical is to be ascertained in accordance with the determination under subsection 99(4) of the Act in respect of the supply of pharmaceutical benefits by public hospitals.

Paragraph 23 provides that regulation 22 and subregulations 25(2), 25(3) and 25(4) do not apply to the supply of chemotherapy pharmaceuticals under these Arrangements.

Paragraph 24 provides that an approved hospital authority must prepare an electronic pharmacy record for each medication chart that has directed the supply of a chemotherapy pharmaceutical to a patient of that hospital, and must retain that record for not less than one year after the day on which the chemotherapy pharmaceutical was supplied.

Paragraph 25 provides that the electronic record prepared in accordance with paragraph 24 must contain all the information required to be included in a prescription record by Part 4 of Schedule 1 to the rules in force under subsection 99AAA(8) of the Act, as modified by paragraph 29 of these Arrangements.

Paragraph 26 provides that, subject to paragraph 27, a claim by an approved hospital authority to the Commonwealth for the supply of a chemotherapy pharmaceutical to a patient of the hospital may be submitted without the medication chart used for the supply of that chemotherapy pharmaceutical.

Paragraph 27 provides that, if the Medicare Australia CEO notifies the approved hospital authority that a copy of the medication charts used for the supply of chemotherapy pharmaceuticals is required to be submitted, the approved hospital authority must submit a copy of each such medication chart to the Medicare Australia CEO.

Paragraph 28 provides that, if the Medicare Australia CEO notifies the approved hospital authority that a copy of the electronic pharmacy records for the supply of chemotherapy pharmaceuticals is required to be submitted, the approved hospital authority must submit a copy of each such electronic pharmacy record to the Medicare Australia CEO.

Paragraph 29 provides that information provided electronically to the Secretary by the approved hospital authority for claims for the supply of chemotherapy pharmaceuticals will conform to the requirements of paragraph 5 of, and Schedule 1 to, the rules in force under subsection 99AAA(8) of the Act, provided that Part 4 of Schedule 1 to those rules is amended by inserting the medical practitioner's "prescriber number" and the "hospital patient indicator" as detailed in subparagraphs 29(a) and 29(b) respectively.

ATTACHMENT 2

SUMMARY OF CHANGES

SCHEDULE 1

Alteration of Circumstances

Docetaxel [addition of circumstance for the treatment of carcinoma of the oral cavity, larynx, oropharynx or hypopharynx]

Dolasetron

Granisetron

Ondansetron

Tropisetron

SCHEDULE 2

Form Added

Fludarabine	Solution for I.V. injection 50 mg fludarabine phosphate in 2 mL

Alteration of Maximum Quantity

		From:	*To:*
Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL	2	1

SCHEDULE 3

Item Added

Docetaxel	Injection set containing 1 single use vial concentrate for I.V. infusion 20 mg (anhydrous) in 0.5 mL and 1 single use vial solvent 1.5 mL