EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

AMENDMENT SPECIAL ARRANGEMENTS UNDER PARAGRAPH 100(1)(b)(i)

IVF/GIFT PROGRAM

No. PB 91 of 2008

Authority for the Arrangements

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 (with the exception of some medicinal preparations with additives) declared by the Minister by legislative instrument to be so under subsection 85(2). These are listed drugs.

The Minister, by legislative instrument, can determine the form or forms of a listed drug by reference to strength, type of unit, size of unit or otherwise (subsection 85(3)); the manner of administration of the form of the listed drug so determined (subsection 85(5)); and a brand of the pharmaceutical item (defined in subsection 84(1)) that has the listed drug in that form with that manner of administration (subsection 85(6)). These determinations govern (except for certain extemporaneously-prepared pharmaceutical benefits) what constitutes the pharmaceutical benefit (defined in subsection 84(1)) under Part VII of the Act.

Subsection 100(1) of the Act empowers the Minister to make special arrangements for the supply of special pharmaceutical products as an alternative to the supply of pharmaceutical benefits under Part VII. This can be done for providing that an adequate supply of special pharmaceutical products will be available to persons who are living in isolated areas; or who are receiving medical treatment in such circumstances that pharmaceutical benefits cannot be conveniently or efficiently supplied in accordance with Part VII, or are inadequate for that medical treatment. A special pharmaceutical product under subsection 100AA(1) is a drug or medicinal preparation declared under subsection 100AA(1), or one composed of one or more of these and a declared additive; or a drug or medicinal preparation which has been declared under subsection 85(2) as a drug or medicinal preparation to which Part VII applies.

Subsection 100(3) provides that Part VII has effect subject to a special arrangement under section 100. This means, for example, that it does not matter if a special arrangement for the supply of a drug declared under subsection 85(2) is inconsistent with determinations relating to the supply of the drug as a pharmaceutical benefit under Part VII.

The drugs which are the subject of these special arrangements (IVF/GIFT Program) are declared under subsection 85(2).

Subsection 100(2) empowers the Minister to vary or revoke a special arrangement made under subsection 100(1).

Purpose of the Arrangements

The Arrangements for the IVF/GIFT Program relate specifically to the supply of special pharmaceutical products required by patients who are receiving in vitro fertilisation or gamete intra-fallopian transfer treatment.

The purpose of the Arrangements is to ensure that an adequate supply of the special pharmaceutical products listed in the Schedule to the Arrangements is available for patients who require in vitro fertilisation or gamete intra-fallopian transfer treatment. Restrictions on the provision of these treatments mean that these drugs cannot conveniently or efficiently be supplied as pharmaceutical benefits under Part VII.

Special circumstances

In Australia, patients undergoing in vitro fertilisation or gamete intra-fallopian transfer treatment must be admitted as in-patients at clinics accredited as Assisted Reproductive Technology (ART) centres.

In accordance with these amended special arrangements, the special pharmaceutical products used in in vitro fertilisation or gamete intra-fallopian transfer treatment are supplied to an ART centre on the basis of evidence of treatment provided to in-patients for in vitro fertilisation or gamete intra-fallopian transfer treatment. Such treatment is evidenced by one of the two item numbers from the *Health Insurance (General Medical Services Table) Regulations 2007* that correspond to the procedures known as in vitro fertilisation or gamete intra-fallopian transfer treatment. Reimbursement for supply of the special pharmaceutical products in the Schedule to the Arrangements is only available to ART centres under these Arrangements on the basis of payment of a Medicare benefit for one of the two item numbers from the *Health Insurance (General Medical Services Table) Regulations 2007*.

The Arrangements do not extend to the supply of the special pharmaceutical products for in vitro fertilisation or gamete intra-fallopian transfer treatment in conjunction with surrogacy arrangements.

This legislative instrument amends the Arrangements for the IVF/GIFT Program which were made on 12 March 2007 with effect from 1 April 2007 (No. PB 26 of 2007). The purpose of these amendments is to remove references to the *Health Insurance (General Medical Services Table) Regulations 2006* and instead refer to the Health *Insurance (General Medical Services Table) Regulations 2007* which came into effect from 1 November 2007*;* and to reflect a change in the form of the drug Choriogonadotropin Alfa.

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

This instrument is expressed to commence on 1 September 2008.

Consultations

The Arrangements were made having regard to advice provided by the Pharmaceutical Benefits Advisory Committee (PBAC), an independent expert body established by section 100A of the Act, which makes recommendations to the Minister for Health and Ageing about which drugs and medicinal preparations should be available as pharmaceutical benefits or as special pharmaceutical products. Part VII of the Act only applies to drugs or medicinal preparations recommended by the PBAC. When making recommendations, 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.

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 functons of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.

The pharmaceutical company that supplies the drug affected by the only substantive change made in this instrument was consulted in relation to the amendment.

ATTACHMENT

Paragraph 1 provides that these Amendment Special Arrangements commence on 1 September 2008.

Paragraph 2 provides that Schedule 1 to this instrument amends PB 26 of 2007.

Schedule 1: sets out the amendments to the Arrangements made under s100(1)(b)(i) of the National Health Act (IVF/GIFT Program) in the instrument known as PB 26 of 2007.

Summary of Changes

References, in paragraphs 3(a), 3(b), 4 and 5 of the Arrangements, to the *Health Insurance (General Medical Services) Table Regulations 2006* are changed to be references to the *Health Insurance (General Medical Services) Table Regulations 2007*.

Reference in paragraph 5 of the Arrangements to rule number 26 of the *Health Insurance (General Medical Services) Table Regulation 2006* is changed to rule 81 of the *Health Insurance (General Medical Services) Table Regulation 2007* to reflect the changes that occurred when the regulations were updated.

The form of the drug Choriogonadotropin Alfa which may be supplied under the Arrangement is amended from:

Powder for injection 250 micrograms vial with solvent,

to

Solution for injection 250 micrograms in 0.5 mL pre-filled syringe.