EXPLANATORY STATEMENT

Issued by the Minister for Health and Ageing

NATIONAL HEALTH ACT 1953

AMENDMENT TO ARRANGEMENTS MADE UNDER SUBPARAGRAPH 100(1)(b)(i) – IVF/GIFT PROGRAM

INSTRUMENT NUMBER PB 12 of 2011

Authority for the Arrangements

This legislative instrument is made pursuant to subsection 100(2) of the *National Health Act 1953* ("the Act") and varies the legislative instrument titled *Arrangements made under subparagraph 100(1)(b)(i) – IVF/GIFT Program* (as amended) ("PB 26 of 2007").

Part VII of 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.

The drugs that are the subject of PB 26 of 2007 have been declared under subsection 85(2) to be drugs or medicinal preparations to which Part VII applies. These drugs are listed in the Schedule to PB 26 of 2007.

PB 26 of 2007 is made under subparagraph 100(1)(b)(i) of the Act and provides for the supply of certain medicines to be made available to persons who are receiving medical treatment in circumstances where pharmaceutical benefits cannot be conveniently or efficiently supplied in accordance with Part VII of the Act.

Subsection 100(3) provides that Part VII has effect subject to a special arrangement under subsection 100(1). This means that a special arrangement made under subsection 100(1) can modify the operation of Part VII in relation to the relevant medicines which are the subject of the arrangement.

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

Purpose of the Arrangements

PB 26 of 2007 provides for special arrangements for the IVF/GIFT Program. These special arrangements relate specifically to the supply of certain medicines required by patients who are receiving in vitro fertilisation or gamete intra-fallopian transfer treatment.

The purpose of these special arrangements is to ensure that an adequate supply of the special pharmaceutical products listed in the Schedule to PB 26 of 2007 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.

Variation

This legislative instrument varies PB 26 of 2007 to allow the addition of the drug Cetrorelix to Part 1 of the Schedule.

This legislative instrument commences on 1 February 2011.

Consultations

PB 26 of 2007 was 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 functions of the PBAC, and that would enable them to contribute meaningfully to the deliberations of the PBAC.