EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

National Health (IVF/GIFT Program) Special Arrangement Amendment Instrument 2014 (No.1)

PB 58 of 2014

Authority

Subsection 100(1) of the *National Health Act 1953* (the Act) enables the Minister to make special arrangements for the supply of pharmaceutical benefits. 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) of the Act provides that Part VII of the Act, and instruments made for the purposes of Part VII have effect subject to a special arrangement made under subsection 100(1).

Purpose

The purpose of this legislative instrument, made under subsections 100(1) and (2) of the Act, is to amend the *National Health (IVF/GIFT Program) Special Arrangement 2011* (PB 93 of 2011) (the Special Arrangement) to make changes to the special arrangement relating to the IVF/GIFT Program.

The purpose of the Special Arrangement is to ensure that an adequate supply of the pharmaceutical benefits 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 pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

This Instrument reflects changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (main listing instrument), which also commences on the same day.

This Instrument:

- adds a new pharmaceutical benefit ‘Progesterone’;
- amends treatment conditions for the listed drug ‘Corifollitropin Alfa’; and
- inserts treatment conditions for all forms of ‘Progesterone’.

Consultation

The Special Arrangement 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 about which drugs and medicinal preparations should be available as pharmaceutical benefits. 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.

Pharmaceutical companies were consulted throughout the process for additions and changes to listings on the PBS and for this Special Arrangement. This includes consultation through the PBAC process, and agreement to final listing details.

This Instrument commences on 1 August 2014.

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

ATTACHMENT

PROVISION BY PROVISION DESCRIPTION OF THE NATIONAL HEALTH (IVF/GIFT PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2014 (No. 1)

Section 1 Name of Instrument

This section provides that this Instrument is the *National Health (IVF/GIFT Program) Special Arrangement Amendment Instrument 2014 (No. 1)* and that it may also be cited as PB 58 of 2014.

Section 2 Commencement

This section provides that this Instrument commences on 1 August 2014.

Section 3 Amendments to PB 93 of 2011

This section provides that Schedule 1 amends the *National Health (IVF/GIFT Program) Special Arrangement 2011* (PB 93 of 2011) (the Special Arrangement).

Schedule 1

Item 1 amends Schedule 1 of the Special Arrangement by adding a new pharmaceutical benefit, which is the listed drug 'Progesterone' in the form 'vaginal tablet 100 mg' with the manner of administration 'Vaginal' and brand 'Endometrin'.

Schedule 3

Item 2 amends Schedule 3 of the Special Arrangement by substituting the treatment conditions for 'Corifollitropin Alfa' in the form 'Solution for injection 100 micrograms in 0.5 mL single dose pre-filled syringes' to be consistent with the treatment conditions for 'Corifollitropin Alfa' in the form 'Solution for injection 150 micrograms in 0.5 mL single dose pre-filled syringes'.

Item 3 amends Schedule 3 of the Special Arrangement by adding treatment conditions for all forms of the listed drug 'Progesterone'.

Statement of Compatibility with Human Rights

Prepared in accordance with Part 3 of the Human Rights (Parliamentary Scrutiny) Act 2011

National Health (IVF/GIFT Program) Special Arrangement Amendment Instrument 2014 (No.1)

This Legislative Instrument is compatible with the human rights and freedoms recognised or declared in the international instruments listed in section 3 of the *Human Rights (Parliamentary Scrutiny) Act 2011*.

Overview of the Legislative Instrument

The purpose of the Special Arrangement is to ensure that an adequate supply of the pharmaceutical benefits 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 pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

This Instrument reflects changes made to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (main listing instrument), which commences on the same day.

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- inserts treatment conditions for all forms of 'Progesterone'.

Human rights implications

This legislative instrument engages Article 2 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) by assisting with the progressive realisation by all appropriate means of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.

The PBS is a benefit scheme which assists with advancement of this human right by providing for subsidised access by patients to medicines. The recommendatory role of the Pharmaceutical Benefits Advisory Committee (PBAC) ensures that decisions about subsidised access to medicines on the PBS are evidence-based.

Conclusion

This Legislative Instrument is compatible with human rights because it advances the protection of human rights.

Kim Bessell
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