**EXPLANATORY STATEMENT**

***NATIONAL HEALTH ACT 1953***

***NATIONAL HEALTH (IVF PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2022 (No. 1)***

**PB 16 of 2022**

**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**

This is the *National Health (IVF Program) Special Arrangement Amendment Instrument 2022 (No. 1)* (the Amendment Instrument). The purpose of the Amendment Instrument is to amend the *National Health (IVF Program) Special Arrangement 2015* (PB 60 of 2015) (the Special Arrangement), to make changes relating to the IVF Program.

The purpose of the Special Arrangement is to ensure that an adequate supply of pharmaceutical benefits is available for patients who require in vitro fertilisation treatment. Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

The amendments made by this Instrument reflect amendments to the *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012), which commence on the same day. The *National Health (Listing of Pharmaceutical Benefits) Instrument 2012* (PB 71 of 2012) is made under sections 84AF, 84AK, 85, 85A, 88 and 101 of the Act.

The amendments made by this Instrument reflect changes made during the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960* (the Regulations), and the addition of forms to the listed drug chorionic gonadotrophin in Schedule 1 of the Special Arrangement.

These changes are summarised, by subject matter, in the Attachment.

**Consultation**

The amendments made by this Instrument accord with recommendations made by the Pharmaceutical Benefits Advisory Committee (PBAC).

An ongoing and formal process of consultation in relation to matters relevant to the Special Arrangement includes the involvement of interested parties through the membership of the PBAC.

PBAC is an independent expert body established by section 100A of the Act 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 PBAC, and that would enable them to contribute meaningfully to the deliberations of PBAC. In addition, an industry nominee has been appointed to the PBAC membership. When recommending the listing of a medicine on the Pharmaceutical Benefits Scheme (PBS), 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.

Pharmaceutical companies were consulted throughout the process of changes to the listings on the PBS. This includes consultation through the PBAC process.

Further consultation for this Instrument was considered unnecessary due to the nature of the consultation that had already taken place in the decision to list the medication.

Details of the instrument are set out in the Attachment.

This Instrument commences on 1 March 2022.

This Instrument is a legislative instrument for the purposes of the Legislation Act 2003.

**ATTACHMENT**

**PROVISION-BY-PROVISION DESCRIPTION OF *NATIONAL HEALTH (IVF PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2022 (No. 1)***

**Section 1 Name of Instrument**

This section provides the name of this instrument as the *National Health (IVF Program) Special Arrangement Amendment Instrument 2022 (No. 1)* and mayalso be cited as PB 16 of 2022.

**Section 2 Commencement**

This section provides that this instrument commences on 1 March 2022.

**Section 3 Amendment of *National Health (IVF Program) Special Arrangement 2015*   
(PB 60 of 2015)**

This section provides that Schedule 1 amends the *National Health (IVF Program) Special Arrangement 2015* (PB 60 of 2015).

**Schedule Amendments**

Item 1

Item 1 amends the definition of ‘*Regulations’* in section 4 of the Special Arrangement to account for the remaking of the *National Health (Pharmaceutical Benefits) Regulations 1960* which commenced on1 April 2017.

Item 2

Item 2 involves the addition of forms for a listed drug to the Special Arrangement. These changes are summarised below.

**SUMMARY OF CHANGES TO THE *IVF PROGRAM*MADE BY THIS INSTRUMENT**

**Forms Added**

|  |  |
| --- | --- |
| ***Listed Drug*** | ***Form*** |
| Chorionic gonadotrophin | Injection set containing powder for injection 1,500 units, 3 and solvent 1 mL, 3 (s19A) |
| Powder for injection 5,000 units with solvent (s19A) |

**Statement of Compatibility with Human Rights**

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

***National Health (IVF Program) Special Arrangement   
Amendment Instrument 2022 (No. 1)***

**(PB 16 of 2022)**

This 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 Instrument**

The purpose of this Instrument, made under subsection 100(2) of the *National Health Act 1953* (the Act), is to amend the *National Health (IVF Program) Special Arrangement 2015 (PB 60 of 2015)* (the Special Arrangement), to make changes to the Special Arrangement relating to the IVF Program.

The purpose of the Special Arrangement is to ensure that an adequate supply of pharmaceutical benefits is available for patients who require in vitro fertilisation treatment. Restrictions on the provision of this treatment mean that these pharmaceutical benefits can more conveniently or efficiently be supplied under a special arrangement.

**Human rights implications**

The Instrument engages Articles 9 and 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), specifically the rights to social security and health.

*The Right to Social Security*

The right to social security is contained in Article 9 of the ICESCR. It requires that a country must, within its maximum available resources, ensure access to a social security scheme that provides a minimum essential level of benefits to all individuals and families that will enable them to acquire at least essential health care. Countries are obliged to demonstrate that every effort has been made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, this minimum obligation.

The UN Committee on Economic Social and Cultural Rights reports that there is a strong presumption that retrogressive measures taken in relation to the right to social security are prohibited under ICESCR. In this context, a retrogressive measure would be one taken without adequate justification that had the effect of reducing existing levels of social security benefits, or of denying benefits to persons or groups previously entitled to them. However, it is legitimate for a Government to re-direct its limited resources in ways that it considers to be more effective at meeting the general health needs of all society, particularly the needs of the more disadvantaged members of society.

*The Right to Health*

The right to the enjoyment of the highest attainable standard of physical and mental health is contained in Article 12(1) of the ICESCR. The Committee has stated that the right to health is not a right for each individual to be healthy, but is a right to a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.

The Committee reports that the ‘highest attainable standard of health’ takes into account the country’s available resources. This right may be understood as a right of access to a variety of public health and health care facilities, goods, services, programs, and conditions necessary for the realisation of the highest attainable standard of health.

**Analysis**

This Instrument advances the right to health and the right to social security by ensuring that the amendments to the Listing Instrument, that affect the pharmaceutical benefits that may be supplied under the Special Arrangement, are made concurrently. This Instrument provides for the addition of forms for the listed drug chorionic gonadotrophin to the Special Arrangement.

The Listing Instrument determines the pharmaceutical benefits that are on the Pharmaceutical Benefits Scheme (PBS) through declarations of drugs and medicinal preparations, and determinations of forms, manners of administration and brands. The PBS is a benefit scheme which assists with advancement of these human rights 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.

**David Laffan**

**Assistant Secretary**

**Pharmacy Branch**

**Technology Assessment and Access Division**

**Department of Health**