EXPLANATORY STATEMENT

NATIONAL HEALTH ACT 1953

NATIONAL HEALTH (IVF PROGRAM) SPECIAL ARRANGEMENT AMENDMENT INSTRUMENT 2021 (No. 2)

PB 123 of 2021

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 2021 (No. 2)* (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 include the addition of brands to the listed drug follitropin alfa 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 December 2021.

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 2021 (No. 2)*

Section 1 Name of Instrument

This section provides the name of this instrument as the *National Health (IVF Program) Special Arrangement Amendment Instrument 2021 (No. 2)* and may also be cited as PB 123 of 2021.

Section 2 Commencement

This section provides that this instrument commences on 1 December 2021.

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

The amendments in Schedule 1 involve the addition of brands for a listed drug to the Special Arrangement. These changes are summarised below.

SUMMARY OF CHANGES

Brands Added

Listed Drug	***Form***
Follitropin Alfa	Injection 300 I.U. in 0.5 mL multi dose cartridge *(Ovaleap)*
	Injection 450 I.U. in 0.75 mL multi dose cartridge *(Ovaleap)*
	Injection 900 I.U. in 1.5 mL multi dose cartridge *(Ovaleap)*

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 2021 (No. 2)

(PB 123 of 2021)

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 right to social security is contained in Article 9 of the International Covenant on Economic Social and Cultural Rights (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 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. The pharmaceutical industry now has a nominee on the PBAC membership.

Whether there is any detriment to patients by the deletion of these drugs, and if so, how this is compatible with the right to social security

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.

Conclusion

The amendment in Schedule 1 involves the addition of a brand to the Special Arrangement and is therefore compatible with human rights as it advances the protection of human rights.

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