

## ARTIFICIAL FERTILISATION ACT NUM. 55, OF MAY 29th, 1996

### *Article 1. Definitions*

*Artificial fertilisation:* Conception resulting from artificial insemination or *in vitro* fertilisation.

*Artificial insemination:* Process whereby sperm are placed in or near the reproductive organs of a woman, other than by sexual intercourse.

*In vitro fertilisation:* Process whereby an ovum, which has been removed from a woman's body, is fertilised by sperm outside the body.

*Gametes:* Ova and sperm.

*Embryo:* Fertilised ovum at all stages of development, from fertilisation until the foetal stage.

*Donor:* Individual who provides another with gametes.

*Surrogacy:* Artificial fertilisation performed on a woman who intends to carry a child for another woman, and has agreed before the pregnancy to give up the child immediately after the birth.

### *Article 2. General Provisions*

Artificial fertilisation may only be carried out at a health institution which has obtained a licence from the minister for that purpose and under the supervision of specialists in gynaecology and obstetrics.

A health institution which has been granted a licence by the terms of paragraph 1 must offer couples who apply for artificial fertilisation, and prospective donors, professional counselling

by specialists, such as social workers or psychologists.

### *Article 3. Artificial Fertilisation May Only be Carried Out if:*

a) The woman undergoing the procedure has been living with a man, married or in a non-formalised relationship, continuously for at least three years, and they have both given written consent in the presence of witnesses.

b) The age of the couple may be deemed natural, *inter alia* with regard to the welfare of the child as he/she grows up.

c) The mental and physical health and the social circumstances of the couple are good.

d) Other procedures to overcome infertility have failed or are unavailable.

Before artificial fertilisation is carried out, and approval is granted as provided in item a paragraph. 1, the couple shall be provided with information on the treatment and its potential medical, social and legal implications.

A physician shall decide whether artificial fertilisation is carried out. A refusal may be appealed to the director of Health, who shall without delay send it on to a special committee appointed by the minister for a period of four years. The committee shall comprise three members, and an equal number of deputies; one lawyer, one physician and one social worker. The committee's decision shall be final.

The minister shall issue more detailed regulations Reg. 568/1997, *cfr.* 585/1997 on the implementation of this provision, *inter alia* on authority to seek the opinion of a child welfare committee on the social circumstances of the couple.

*Article 4. The Physician Providing treatment Shall Choose a Suitable Donor*

Should a donor request anonymity, health workers must ensure that this wish be respected. In such cases information may not be provided to the donor on the couple receiving donor gametes, nor about the child, nor may the couple or the child receive information on the donor.

Should the donor not request anonymity, the institution shall keep information on the donor in a special file. Should the donation of gametes result in the birth of a child, data on the child and on the couple who received the donated gametes shall be kept in the same file.

A child conceived as a result of a donation of gametes, where the donor did not request anonymity, may at the age of 18 request access to the records as provided in paragraph. 3, in order to acquire information on the name of the donor. Should a child receive information on the gamete donor from the institution, the institution shall, as soon as possible, inform the donor that the information has been provided.

*Article 5. Artificial Insemination using Donor Sperm*

Artificial insemination with donor sperm may only be carried out if the

fertility of the man is impaired, if he has a serious hereditary disease, or if there are other medical reasons for use of donor sperm.

*Article 6*

*In vitro* fertilisation may only be carried out with the gametes of the couple. It shall however be permitted to use donor gametes if the fertility of the man or the woman is impaired, if either of them has a serious hereditary disease or there are other medical reasons for use of donor gametes.

Donation of embryos is not permitted.

Surrogacy is not permitted.

*Article 7*

Storage of gametes and embryos is only permitted at a health institution licensed by the minister to carry out artificial fertilisation, cp. article 2.

*Article 8*

Gametes may only be stored for the purpose of:

- a) The parties' own use at a later time.
- b) Donation for research purposes.
- c) Donation of gametes for use in artificial fertilisation.

The person who provides gametes shall give written consent for their storage in accord with the purpose of storage, after having received information on the effect of storage on the gametes, and on the general rules applying to storage of gametes in this Act and in rules issued on the basis of the Act.

*Article 9*

Embryos may be stored for the purpose of transplanting them into the woman who provided the ova, or the wife of, or women cohabiting with, the man who provided the sperm. The storage of embryos for other purposes is prohibited.

Storage of embryos is subject to the condition that the man and the woman providing the gametes give their written consent for storage which is in keeping with the stated purpose, provided that they have previously received information on how the storage affects the embryos and on the general conditions regarding the storage of embryos laid down in this Act and rules based on the Act.

Embryos may only be used in accord with the wishes of those providing the gametes.

*Article 10*

The minister shall issue rules Reg. 568/1997 on how long gametes and embryos may be stored, in accord with the best medical knowledge at the time.

At the end of the maximum storage period, unused gametes and embryos shall be destroyed.

Should the person who provided gametes die before the expiry of the maximum storage period, unused gametes shall be destroyed, unless the purpose of the storage was to donate gametes for use in artificial fertilisation.

Should the man and woman who provided gametes separate or be divorced before the expiry of the maximum

storage period for embryos, the embryos shall be destroyed. The same applies if one of the couple dies, unless the gametes were donated for use in artificial fertilisation.

*Article 11. Research on Embryos*

All research, experiments and operations on embryos is prohibited.

Nevertheless, it is permitted to carry out research on embryos:

- a) If it is part of an *in vitro* fertilisation treatment.
- b) If the intention is to diagnose hereditary diseases in the embryos themselves.
- c) If the purpose is to advance the treatment of infertility.
- d) If the purpose is to improve understanding of the causes of congenital diseases and miscarriages.

*Article 12*

It is prohibited to:

- a) Cultivate or produce embryos solely for research purposes.
- b) Cultivate embryos for more than 14 days outside the body or once the primitive streak has appeared.
- c) Transplant human embryos into animals.
- d) Perform cloning.

*Article 13. Final Provisions*

The minister shall issue more detailed rules Reg. 568/1997 on the implementation of this Act. These shall cover, *inter alia*:

- a. Preparation of prospective parents for the treatment, including their access to counselling.

- b. Use of donor gametes, including use of donor gametes within the family.
- c. Storage period of embryos.
- d. Scientific research on embryos, cf. items c and d, article 11, and a Bioethics Committee to control such research.

#### *Article 14*

Violation of the provisions of this Act or of rules based on it entails fines or imprisonment of up to three months under the terms of this Act.

Participation in such a violation shall entail the same penalties, unless more severe penalties apply under other legislation.

#### *Article 15*

This Act shall take force on 1 june 1996, and at that time rules shall be in existence as provided in article 13 on the practice of artificial fertilisation, issued by the minister.