Regulation num. 568/1997 on Artificial Fertilisation Act

Article 1. Definitions

Artificial fertilisation: Conception as a result of artificial insemination or *in vitro* fertilisation.

Artificial insemination: Process whereby the sperm is placed in or near the genitalia of a woman by other means than copulation. In vitro fertilisation: Process whereby the ovum which has been removed from the woman's body is fertilised with the sperm outside the body.

Gamete: Ova and sperm.

Embryo. Fertilised ovum in any stage of development, from the time of fertilisation until it develops into a foetus.

Donor: An individual providing another individual with gamete. Surrogacy: Artificial fertilisation of a woman who intends to carry a child for another woman and who has consented to it before the pregnancy to give the baby up immediately after the birth.

Scientific research: Research conducted with the aim to achieve further knowledge, making it, *inter alia*, possible to improve health and cure diseases. An evaluation of the research made by the Scientific Ethics Committee or an ethics committee, pursuant to article 29 of Act num. 74/1997 on the Rights of Patients, must have revealed that scientific and ethical views do not oppose its implementation.

Article 2

Artificial fertilisation may only be carried out in a health institution which has obtained a license from the minister for that purpose and is operated under the supervision of a gynaecologist and obstetrician.

Article 3

Artificial fertilisation must only be carried out if the following conditions have been met:

a) A woman undergoing the operation must have been married continuously for at least three years or cohabiting with a man continuously for at least three years.

b) A woman undergoing the operation and her husband or cohabitant must have applied for artificial fertilisation and their formal consent to have the operation must have been testified on a special form issued by the relevant health institution for this purpose.

c) As a rule, both partners shall be 25 years of age at the commencement of the treatment. As a rule, the woman shall not be older that 42 years at the commencement of the treatment. It is permitted to derogate from the specified age condition of the woman if a stored embryo, stored ovum or donor ovum is being used. The woman shall, however, never be older than 45 years

when the embryo is transplanted and the husband or cohabitant, as a rule, shall not be older than 50 years.

d) The mental and physical health and the social conditions of the couple shall be sound.

e) Other operations to overcome infertility must have failed or be unavailable.

Article 4

A couple requesting artificial fertilisation shall apply for it on a form pursuant to article 3 (b). A doctor decides if the artificial fertilisation will take place. During an evaluation of whether a couple applying for artificial fertilisation meets the condition of article 3 (d), their ability to ensure conditions favourable to the development of the child shall be taken into consideration. If the doctor believes it necessary, he is obliged, with the consent of the couple, to insist on a certificate from the relevant experts regarding the mental and physical health of the couple. In the same manner, he shall insist on certificates from a social worker or another person who is able to provide information on the social conditions of the couple. If the couple does not consent to the aforementioned gathering of information, the doctor is authorised to decline artificial fertilisation. If the doctor has reservations as to whether the social conditions of the couple are satisfactory with regard to the upbringing of a child he can seek the opinion of child welfare authorities.

Article 5

Once an application for artificial fertilisation has been approved, the couple shall before an approval pursuant to article 3 (b) is given, be provided with information on the treatment and any possible medical, social and legal implications. The information shall be given both verbally and in writing on a special form, *cfr*. article 3 (b).

Article 6

If a doctor refuses artificial fertilisation, a complaint may be filed with the Directorate General of Public Health. The time limit to file the complaint is three months from the date of communication of the refusal. The Directorate General of Public Health shall without delay send the complaint to a special committee appointed by the minister for a period of four years at a time. The committee shall be made up of three representatives, and an equal number of substitutes, thereof one lawyer, one doctor and one social worker. The decision of the committee is final.

Article 7

Before the artificial fertilisation is carried out, the health institution in charge of the operation shall inform the couple in question about the possibility of professional counselling by psychologists or social workers and the institution shall provide it if the couple requests such counselling.

Article 8

Artificial insemination with donor sperm shall only be carried out if the fertility of the man is impaired, he has a serious hereditary disease or there are other medical reasons to use of donor sperm.

Article 9

In vitro fertilisation shall only be carried out with the gamete of the couple. It is however permitted to use donor gamete if the fertility of the man or the woman is impaired, either of them has a serious hereditary disease or there are other medical reasons to use of donor gamete. It is prohibited to carry out *in vitro* fertilisation unless the gamete of either partner or either cohabitant is used. Donation of embryos and surrogacy is prohibited.

Article 10

Storage of gamete and embryos is only permitted in health institutions licensed by the minister to carry out artificial fertilisation.

Article 11

Gamete can only be stored for the purpose of:

a) Personal use at a later time.

b) Donation for research purposes, or

c) Donation of gamete for use in artificial fertilisation.

Article 12

A person providing gamete shall formally consent to the storage which is in keeping with the stated purpose, provided that he or she has received information on how the storage affects the gamete and the general conditions regarding the storage of gamete laid down in acts on artificial fertilisation and in this Regulation.

Article 13

It is permitted to store embryos for the purpose of transplanting them into the woman who provided the ova or the wife or the cohabitant of the man who provided the sperm. The storage of embryos for other purposes is prohibited.

Article 14

Embryos may be stored on the condition that the man and the woman providing the gamete give their formal consent for the storage which is in keeping with the stated purpose, provided that they have previously received information on how the storage affects the embryos and the general conditions regarding the storage of embryos laid down in acts on artificial fertilisation and this Regulation. Embryos can only be used in accordance with the consent of those providing the gamete.

Article 15

Before a stored embryo is transplanted into the uterus of a woman who provided the ova or the wife or the cohabitant of a man who provided the sperm, their formal consent shall be sought again. The same applies when artificial insemination is carried out with the sperm of a husband or a cohabitant which has been stored for later use.

Article 16

Embryos may be stored for a maximum of five years. At the end of five years, unused embryos shall be destroyed. Gamete may be stored for a maximum of 10 years. At the end of that time, unused gamete shall be des-

troyed. When the gamete of a man or a woman are stored for personal use at a later time due to foreseeable infertility caused by a disease, they can apply for an extension if they have not had the opportunity to use the gamete as they have not met the conditions of article 3 (a) and/or article 3 (c)(1). An application for extension shall be submitted to the relevant health institution. In case of a refusal, a complaint may be submitted to the Directorate General of Public Health and the procedure provided for in article 6 of this Regulation shall be applicable. If a person providing the gamete has died, unused gamete shall be destroyed, unless the purpose of the storage had been to donate the gamete for use in artificial fertilisation. If a man and a woman who provided the gamete end their marriage or their cohabitation, or either of them dies, the embryos shall be destroyed. The owners of stored embryos and the owners of gamete shall, at the beginning of the storage period, be informed about the aforementioned rules on the maximum storage time, verbally and in writing.

Article 17

If donated gamete are used, the doctor in charge of the treatment shall select the appropriate donor. A donor of gamete shall be healthy and have no hereditary diseases. Necessary tests shall be carried out to ensure that the donor is healthy and fertile and to prevent the transmission of diseases with the gamete. If imported gamete are used, the fulfilment of the aforementioned demands must be ensured. A doctor shall endeavour to realise the wishes of applicants that the build, height, colour of eyes and hair and the blood type of the gamete donor is as closely resembling the parent's as is possible.

Article 18

If a donor wishes to remain anonymous, health workers are obliged to ensure that this is respected. In this case, the donor may neither receive information about the couple receiving the donated gamete or the child, nor the couple or the child receive information about the donor. If a donor does not wish to remain anonymous, the institution shall preserve information about him in a special file. If the donation of gamete leads to the birth of a child, information about the child and the couple who received the gamete shall be kept in the same file. A child born on account of a gamete donation where the donor does not wish to remain anonymous, can at the age of 18 gain access to a file pursuant to paragraph 2 for the purpose of obtaining information about the identity of the donor. If a child receives information about the gamete donor at the institution, the said institution shall as soon as possible inform the donor that the information has been given.

Article 19

The prospective donor shall receive clear information beforehand on the following issues, verbally and in writing:

a) What the gamete donation entails.

b) That he can request anonymity.

c) The rules that apply on the one hand to anonymity and on the other hand to revealing the identity.

d) The medical and ethical problems that could arise in connection to donating gamete.

e) His or her legal status and that of the child that might be born as a result.

If the gamete is donated within the family, the donor shall receive counselling beforehand regarding the specific problems the donor, recipients and the prospective child might possibly encounter.

Article 20

A couple that has applied for artificial fertilisation where donated gametes are used shall receive clear information about the following issues, verbally and in writing:

a) What the gamete donation entails.

b) His or her legal status and that of the prospective child.

c) Whether the donor does or does not wish to remain anonymous and what rules are applicable in each case.

d) That they have the right to receive professional counselling both before the operation and due to problems that might arise later as a result of the artificial fertilisation or the gamete donation.

e) That the husband or cohabitant is considered to be the father of the child conceived as a result of the artificial fertilisation although donated sperm is used.

f) That the wife or cohabitant is considered to be the mother of the child conceived as a result of the artificial fertilisation although donated ovum is used.

Both parties shall receive information about the aforementioned issues before they give their consent pursuant to article 21. Both parties shall give their formal consent on the one hand regarding the artificial fertilisation and regarding gamete that has been donated on the other hand. When donated gametes are used in the artificial fertilisation, it must be ensured that the donor and the couple in question receive information about the medical and ethical problems that could arise in connection to the donation and reception of gamete. Furthermore, the parties shall receive clear information about their legal status and that of the child that might be born as a result.

If the gamete is donated within the family, the couple shall receive counselling beforehand regarding the specific problems the donor, recipients and the prospective child might possibly encounter.

Article 21

Before artificial fertilisation with donated gamete takes place, both parties shall specially give their testified consent in writing regarding the use of donated gamete in the artificial fertilisation.

Article 22

Any research, experiments and operations on embryos shall be prohibited.

Nevertheless, it is permitted to do 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 increase understanding of the causes of innate diseases and miscarriages.

It is prohibited to carry out research pursuant to points c) and d) unless it meets the conditions of article 1 (8) on scientific research and the approval of the Scientific Ethics Committee or ethics committees has been obtained pursuant to article 29 of Act num. 74/1997 on the Rights of Patients.

Article 23

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 24

Infringement of these rules is subject to fines or imprisonment of up to three months, cf. article 14 of Act num. 55/1966 on Artificial Fertilisation.

Participation in such an infringement shall be punishable in the same way unless it is subject to a more severe punishment according to other laws.

Article 25

This Regulation is laid down pursuant to article 13, *cfr*. article 3 and 10 of Act num. 55/1996 on Artificial Fertilisation, and enters into force immediately. At the same time, the working procedure of the Fertility Ward at the National Hospital of 21 april 1995 and Rules on the Freezing of Embryos of 14 december 1995 cease to apply.

The Ministry of Health
and Social Security,
30 september 1997