

# **The Act relating to the application of biotechnology in medicine**

Act No. 56 of 5 August 1994

## **Chapter 1 Purpose and scope of the Act**

### *Section 1-1 (Purpose of the Act)*

The purpose of this Act is to ensure that the application of biotechnology in medicine is utilized in the best interests of human beings in a society where everyone plays a role and is fully valued. This shall take place in accordance with the principles of respect for human dignity, human rights and personal integrity and without discrimination on the basis of genetic background, on the basis of ethical norms relating to our western cultural heritage.

### *Section 1-2 (Scope of the Act)*

The Act applies to the application of biotechnology in medicine in relation to human beings.

## **Chapter 2 Assisted procreation**

### *Section 2-1 (Definition)*

For the purpose of this Act, assisted procreation shall be understood to refer both to insemination by donor and to in vitro fertilization.

For the purpose of this Act, insemination by donor is defined as the introduction of sperm into a woman by methods other than sexual intercourse.

For the purpose of this Act, in vitro fertilization is defined as the fertilization of eggs outside the woman's body.

### *Section 2-2 (Required forms of cohabitation)*

Assisted procreation treatment may only be given to a woman who is married or living in a stable partnership with a man.

*Section 2-3 (Consent)*

Before treatment is embarked on, written consent shall be obtained from the woman and her husband or partner.

The physician providing the treatment shall ensure that the consent is still valid at the beginning of the treatment.

*Section 2-4 (Decision and information concerning the treatment)*

The decision to undertake treatment with a view to assisted procreation shall be made by a physician. The decision shall be based on medical and psychosocial assessment of the couple.

The couple shall be given information about the treatment and the medical and legal consequences it may have.

*Section 2-5 (Storage and import of sperm)*

Only institutions which, pursuant to section 8-1, are authorized to carry out assisted reproduction technology may freeze or by other means store sperm.

Sperm may only be imported when permission has been given by the Norwegian Board of Health.

*Section 2-6 (Selection of sperm donor)*

The physician providing the treatment shall select a suitable sperm donor.

*Section 2-7 (Identity of sperm donor, child and couple)*

The medical staff are under an obligation to ensure that the sperm donor's identity is kept secret.

A sperm donor shall not be given information concerning the identity of the couple or the child.

*Section 2-8 (Primary sex selection)*

The treatment of sperm before procreation with a view to determining the gender of the child is only allowed if the woman is a carrier of a serious sex-linked hereditary disease.

*Section 2-9 (Conditions for donor insemination)*

Donor insemination may take place when the husband or partner is infertile and suffers from or is a carrier of a serious hereditary disease.

In special cases, assisted insemination may also take place if the woman is a carrier of a serious sex-linked hereditary disease, cf. section 2-8.

*Section 2-10 (Conditions for in vitro fertilization)*

In vitro fertilization may only take place in cases where the woman or her husband or partner is infertile or in cases of infertility for which no cause has been identified. Such treatment may only be carried out with the couple's own oocytes and sperm.

In vitro fertilization may also take place in cases of serious hereditary disease pursuant to more detailed provisions laid down by the Ministry, cf. section 4-2.

*Section 2-11 (Utilization of embryos)*

Embryos may only be used for implantation into the woman from whom the oocytes originate.

*Section 2-12 (Storage of embryos and prohibition of the storage of oocytes)*

Only institutions which are authorized pursuant to section 8-1 to perform in vitro fertilization may store embryos.

Embryos may not be stored for more than three years.

Storage of oocytes is prohibited.

*Section 2-13 (Permission for assisted procreation treatment)*

Forms of treatment under § 2-1 shall be subject to permission from the Ministry.

Before the Ministry decides whether or not to grant permission, the matter shall be submitted to the Biotechnology Advisory Board for comment, cf. section 8-4.

## **Chapter 3 Research on embryos**

### *Section 3-1 (Prohibition of research on embryos)*

Research on embryos is prohibited.

## **Chapter 3 a Production of genetically identical individuals**

*Section 3a-1 Prohibition of the use of techniques aimed at the production of genetically identical individuals.*

The use of techniques aimed at the production of genetically identical individuals is prohibited.

## **Chapter 4 Preimplantation diagnosis**

*Section 4-1 (Definition)*

For the purpose of this Act, preimplantation diagnosis is defined as the genetic examination of an embryo before it is implanted in the uterus.

*Section 4-2 (Application of preimplantation diagnosis)*

The genetic examination of an embryo may only take place in special cases, where there is incurable hereditary disease with no possibility of treatment, cf. section 2-10. The King may lay down further conditions for undertaking preimplantation diagnosis.

*Section 4-3 (Sex selection)*

It is prohibited to examine an embryo for the purpose of selecting the gender of the child, except in cases of incurable sex-linked hereditary disease.

*Section 4-4 (Genetic counselling and information)*

The woman or couple shall receive genetic counselling and information before preimplantation diagnosis is undertaken.

## **Chapter 5 Prenatal diagnosis**

*Section 5-1 (Definitions)*

For the purpose of this Act, prenatal diagnosis is defined as

- a) examination of the fetus or pregnant woman to detect or exclude genetic disease or developmental anomalies,

b) ultrasound examination of a pregnant woman.

*Section 5-2 (Permission for prenatal diagnosis)*

Tests and methods of examination pursuant to section 5-1, litra a, for the purpose of detecting or excluding genetic disease or developmental anomalies shall be subject to the permission of the Ministry.

*Section 5-3 (Genetic counselling and information)*

Before prenatal diagnosis is undertaken, the woman or the couple shall be informed that the examination is voluntary and given information on what can be detected by means of the examination and the consequences the findings may have for the child, the woman, the couple and the family.

*Section 5-4 (Information about the gender of the fetus)*

Information about the gender of the fetus resulting from prenatal diagnosis as described in section 5, litra a, before the 12th week of pregnancy shall be given only if the woman is a carrier of a serious sex-linked disease.

## **Chapter 6 Genetic testing after birth**

*Section 6-1 (Definitions)*

For the purpose of this Act, genetic testing after birth is defined as:

- a) genetic tests for diagnosing a disease,
- b) genetic tests for presymptomatic diagnosis,
- c) genetic tests for predictive diagnosis,
- d) genetic tests to detect or exclude healthy carriers of hereditary diseases,
- e) genetic laboratory tests for gender verification, except genetic laboratory tests for the purpose of identification.

*Section 6-2 (Application of genetic testing)*

Genetic testing may only be carried out for medical purposes when it has a diagnostic and/or therapeutic objective.

*Section 6-3 (Permission for genetic testing)*

Tests and methods as described in section 6-1, litrae b, c, and d, are subject to the special permission of the Ministry.

Before the Ministry decides whether or not to grant permission, the matter shall be submitted to the Biotechnology Advisory Board for comment, cf. section 8-4.

*Section 6-4 (Consent)*

Before genetic testing as defined in section 6-1, litrae b, c and d, is undertaken, written consent must be obtained from the person who is to be tested.

The result of a genetic test as defined in section 6-1, litrae b, c, and d, may not be registered without the consent of the person to whom the result applies.

Genetic testing of a child under the age of 16 years may only be carried out with the consent of the parents or guardians.

*Section 6-5 (Genetic counselling and information)*

In the case of genetic testing after birth, the person undergoing the genetic test shall be given comprehensive genetic counselling before, during and after the test is carried out.

If the person undergoing the genetic test is under the age of 16 years, the genetic counselling shall also be given to the parents or guardians.

Diagnostic information obtained from genetic testing in accordance with section 6-1, litra a, and from gender laboratory tests for gender verification in accordance with section 6-1, litra e, is excepted from the provisions of the first paragraph.

*Section 6-6 (Genetic testing of children)*

Genetic testing of a child under the age of 16 years shall not be carried out unless the test is able to detect a condition that by means of treatment can prevent or reduce damage to the child's health.

If an early diagnosis can contribute to a significant improvement in prognosis, the parents may demand that the test be performed.

Diagnostic information obtained from genetic testing in accordance with section 6-1, litra a, and from gender laboratory tests for gender verification in accordance with section 6-1, litra e, is excepted from the provisions of the first paragraph.

*Section 6-7 (Prohibition of the use of genetic information)*

It is prohibited to request, receive, possess or make use of genetic information resulting from a genetic test on any person.

It is prohibited to ask whether a genetic test has been carried out.

The prohibitions in the first and second paragraphs do not apply to medical institutions which are authorized pursuant to section 8-1 to carry out genetic testing as described in section 6-1, or for research purposes. If genetic information is to be used for research purposes, consent must be obtained from the person whom the information concerns.

Diagnostic information obtained from genetic testing in accordance with section 6-1, litra a, and from gender laboratory tests for gender verification in accordance with section 6-1, litra e, is excepted from the provisions of the first paragraph.

The prohibitions in the first and second paragraphs do not apply to medical practitioners who need genetic information for diagnostic and therapeutic purposes.

## **Chapter 7 Gene therapy**

*Section 7-1 (Conditions for gene therapy)*

The human genome may only be altered by means of somatic gene therapy for the purpose of treating serious disease or preventing serious disease from occurring.

Germline therapy is prohibited.

*Section 7-2 (Permission for gene therapy)*

Forms of treatment to which the provisions of section 7-1, first paragraph, apply shall be subject to the permission of the Ministry.

Before the Ministry decides whether or not to grant permission, the matter shall be submitted to the Biotechnology Advisory Board for comment, cf. section 8-4.

*Section 7-3 (Consent)*

Before gene therapy is embarked on, written consent shall be obtained from the person who is to be treated. Before gene therapy is administered to a child under the age of 16 years, consent shall be obtained from the parents or guardians.

## **Chapter 8 General provisions**

### *Section 8-1 (Authorization of institutions)*

Medical application of biotechnology pursuant to the provisions of the Act may only take place at institutions specifically authorized for this purpose by the Ministry. The decision granting authorization shall specify which forms of medical biotechnology the institution has permission to apply.

The Ministry may lay down further conditions for authorization in the decision.

### *Section 8-2 (Duty to report)*

All institutions authorized pursuant to section 8-1 shall submit to the Ministry written reports on their activities.

The Ministry may lay down further provisions concerning the duty to report.

### *Section 8-3 (Regulations)*

The King may issue regulations to supplement and implement the Act.

### *Section 8-4 (The Norwegian Biotechnology Advisory Board)*

The King shall appoint a board to express its views on matters covered by this Act and other questions concerning biotechnology, on request or ex officio. The opinions of the board shall be public unless otherwise required by the statutory duty of secrecy.

The King may issue more detailed rules concerning the board's activities.

*Section 8-5 (Penalties)*

Any person who intentionally contravenes the provisions prescribed in or pursuant to this Act shall be liable to fines or imprisonment for a term not exceeding three months. Any person acting as accessory is liable to the same penalty.

*Section 8-6 (Transitional provisions)*

For activities to which the present Act applies and which are already in progress when the Act enters into force, an application for permission shall be submitted before a date decided by the King.<sup>1</sup> Provided that the application has been submitted before this date, such activities may continue until the application has been dealt with.

*Section 8-7 (Entry into force)*

This Act enters into force on the date decided by the King.<sup>2</sup>

On the same date, the following amendments to other Acts shall enter into force:

1. Act No. 68 of 12 June 1987 relating to artificial procreation is repealed.
2. Section 9, third and fourth paragraphs, of Act No. 8 of 8 April 1981 relating to children and parents (the Children Act) shall read as follows:

If the mother has undertaken donor insemination, and the husband or partner has given his consent to the insemination, a court shall pronounce him to be the father, provided it is not improbable that the child was conceived as a result of the insemination.

The sperm donor may not be pronounced by a court to be the father. However, this does not apply if the insemination has been effected with sperm from the husband or partner and it is not improbable that the child was conceived as a result of the insemination.

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<sup>1</sup>1 november 1994

<sup>2</sup>1 september 1994