

# **Austrian Gene Technology Act – Provisions on Genetic Testing**

## **Definitions**

### **Art. 4. ...**

(23) Genetic testing: laboratory analysis giving evidence on concrete properties regarding number, structure or sequence of chromosomes, genes or DNA-fragments or else regarding DNA-products and specific chemical modifications thereof, thereby, due to new scientific knowledge and technical progress, providing information on a carrier status, a risk of a disease, an existing disease or a course of an illness or of a therapy on man.

## **IVth SECTION - Genetic Testing and Gene Therapy on Man**

### **Prohibition of interventions into the inheriting material of the human germ line**

**Art. 64.** For interventions into the human germ line the prohibition of Art. 9 para. 2 of the Reproductionmedicine Act, BGBl. Nr. 275/1992, is valid.

### **Genetic testing on man for medical purposes**

**Art. 65.** Genetic testing on man for medical purposes is only allowed to be performed due to new scientific knowledge and technical progress. Genetic tests are classified into 4 types:

1. Type 1 serves the determination of a manifested disease, as preparation of a therapy or of the course of a therapy and is based on information about concrete somatic changes of number, structure, sequence or specific chemical modifications thereof of chromosomes, genes or DNA-fragments.
2. Type 2 serves the determination of a manifested disease, which is based on a germ line mutation.
3. Type 3 serves the determination of a predisposition for a disease, in particular the disposition for a potential future onset of a genetically based disease or the determination of a carrier status, for which, due to new scientific knowledge and technical progress, a prophylaxe or therapy is possible.
4. Type 4 serves the determination of a predisposition for a disease, in particular the disposition for a potential future onset of a genetically based disease or the determination of a carrier status, for which, due to new scientific knowledge and technical progress, no prophylaxe or therapy is possible.

(2) Testing of relatives (Art. 70) may be examinations of type 2, 3 or 4.

### **Genetic testing on man for scientific purposes and for education**

**Art. 66.** (1) Genetic testing on man for scientific purposes and for education is only allowed to be performed with explicit informed consent of the proband in written form or on specimen being anonymized. A specimen serving scientific purposes is even then considered to be anonymous, if it is supplied without a name but only with a code which solely can be related to the name of the proband in the respective facility.

(2) The results from genetic tests according to para. 1 are only allowed to be networked or published, if it is ensured through appropriate measures that – irrespective para. 1 - the proband cannot be identified.

(3) A written withdrawal of the informed consent according to para.1 is possible at any time.

### **Prohibition of the collection and use of data from genetic tests for certain purposes**

**Art. 67.** Employers and insurers including authorised representatives and coworkers thereof are prohibited to collect, to demand, to accept or else to make use of results from genetic tests of their employees, job applicants or insurees or insurance canvassers. This prohibition also covers the demand for delivery and the acceptance of body substances for genetic test purposes.

### **Performance of genetic tests on man for medical purposes – official proceeding**

**Art. 68.** (1) The performance of genetic tests in the sense of art. 65 para. 1 fig. 3 and 4 is only allowed to be performed in therefor approved facilities and only at the instance of a medical specialist trained in human genetics/medical genetics or of an attending or diagnosing medical specialist being competent for the respective indication.

(2) The approval has to be applied at the Federal Ministry of Health and Women by the head of the facility in which the performance of such genetic tests is intended.

(3) The approval has to be granted by the minister of health and women after hearing of the competent scientific advisory committee – if necessary by determining appropriate conditions and requirements – if, in respect of the personal and technical equipment and the protection of genetic data thereby incurred according to art. 71, a performance of genetic tests due to new scientific knowledge and technical progress is guaranteed.

(4) The minister of health and women has to withdraw the approval, if the prerequisites for its granting are not valid any more, or else has to impose adequate restraints in the case of the existence of serious insufficiencies with the order attached thereto, not to perform genetic tests according to art. 65 para. 1 fig. 3 or 4 until these conditions are being fulfilled.

### **Head of the facility and laboratory manager**

**Art. 68a.** (1) The head of the facility has to appoint one laboratory manager for each facility performing genetic tests type 2, 3, or 4. That one can be identical with the head of the facility. The head of the facility has to submit a written notification of the laboratory manager to the public authority with attachment of required certificates for this announced person (para. 2).

(2) The laboratory manager has to

1. be a medical specialist for human genetics/medical genetics or for medical-chemical laboratory diagnostics, or
2. have a university degree in natural sciences, including an education in molecular genetics or molecular biology, as well as an expert knowledge of at least two years in molecular genetic testing on man, or

3. have a training as medical specialist, including an education in human genetics/medical genetics, as well as an experience/expert knowledge of at least two years in molecular genetic testing on man, or

4. have a training as medical specialist, that is - as far as he confines himself to genetic tests within the scope of a medical speciality – required for that speciality, including an education in human genetics/medical genetics, as well as an experience/expert knowledge of at least two years in molecular genetic testing on man.

(3) The laboratory manager is responsible for the continuous instruction of co-workers as well as the management and supervision of the performance of the genetic tests. In doing so he has to take measures for data protection and quality assurance, in particular the participation in external quality assessment schemes, being appropriate for the laboratory and has to care for their observance. For that purpose, if at the time of the approval of the facility (art. 68 para. 3) no external quality assessment schemes have been offered, he regularly, in intervals of six months at the most, has to ask the competent authority, if adequate external quality assessment schemes are already offered.

(4) If the laboratory manager quits his function or his appointment is cancelled by the head of the facility, a new laboratory manager has to be appointed without delay.

(5) The head of the facility has to notify the competent authority in writing about a retirement or each change of the laboratory manager without delay, in attaching the required certificates of competence (para. 2) of the substitute person having been appointed by the head of the facility.

(6) Through the appointment of a laboratory manager the responsibility of the head of the facility for the compliance with regulations of this federal act and the public acts to be based thereupon is not concerned.

### **Informed consent and counselling**

**Art. 69** (1) A genetic test of type 2, 3 or 4, including a genetic test in the course of a prenatal diagnosis, is only allowed to be performed if there exists a written consent of the person to be tested, that he or she has been informed in advance about the genetic test's nature, consequences and significance by a medical specialist with an education in human genetics/medical genetics or a medical specialist competent for the respective speciality and if that person has agreed to the genetic test as a result of a free consent based on that knowledge. If the tests are performed prenatally, information and consent of the pregnant person also have to include the risks of the planned intervention.

(2) A confirmation according to para. 1 is given

1. for a mature underage person by this person itself in accordance with art. 146c ABGB
2. for an underage person by a legal guardian and
3. for a person for whom a solicitor is appointed, whose scope comprises the consent for a genetic test, by this solicitor.

(3) Before a genetic test according to para. 1 is performed a detailed genetic counselling of the person to be tested, if need be as well as of the legal guardians or the solicitor being authorised for procuration according to para. 2, about nature, consequences and significance of the genetic test has to take place by the medical specialist trained in human

genetics/medical genetics or the medical specialist competent for the respective speciality, initiating this genetic test to be performed.

(4) Genetic counselling after the performance of a genetic test according to para. 1 has to include an issue-related comprehensive discussion of all test results and medical facts as well as possible medical, social and psychological consequences. In terms of a relevant predisposition for a hereditary disease with serious physical, mental or social consequences it has to be referred to the usefulness of an additional nonmedical counselling by a psychologist or a psychotherapist or by a social worker in written form. Additionally it can be referred to other counselling facilities and self-helping groups.

(5) Genetic counselling before and after a genetic test according to para. 1 is not allowed to be directive. The consulter has to be informed already at the beginning of the counselling interview, that he can communicate anytime – even after having given consent for a genetic test or after counselling has taken place– that he does not want to know the results of the test and of the consequences deduced thereof.

(6) Counselling before and after the performance of a genetic test according to para. 1 has to be concluded with an individual counselling letter to the consulter, which summarises the essential contents of the counselling interview in a generally understandable manner.

### **Involvement of relatives**

**Art. 70.** The physician initiating the genetic test has to recommend the tested person to advise their relatives, who probably are concerned, to undergo a human genetic test and a genetic counselling

1. if for the evaluation of the result from the genetic test the involvement of relatives of the tested person is required
2. if it is to be supposed that there is a serious risk for getting a disease for relatives of the tested person.

### **Data protection**

**Art. 71.** (1) A person who is performing or initiating genetic tests has to keep secret personal data resulting therefrom and has to obey the following rules:

1. On demand of the tested person this person has to be allowed to look at all data concerning him- or herself.
2. Unexpected results with direct clinical relevance or results the tested person has explicitly asked for have to be communicated to that tested person. The communication of such results has to occur in that way, that it will not have a disturbing effect on the tested person, in particular if the tested person has not asked for it; in critical cases such a communication may completely be omitted.
3. Data in a non anonymised form (art. 66 para. 1) may not be used for another purpose as for that which they have originally been collected for, unless the tested person gives an explicit written consent to do so.

4. Irrespective of regulations according to art. 71a on the documentation of test results data only may be passed on

a) to members of the facility where the data have been collected, who are directly involved with the collection, processing and evaluation of these data

b) to the tested person

c) to a person stated in art. 69 para. 2

d) to the physician who has initiated the genetic tests and to the attending physician

e) to another person only if the tested person has explicitly given a written consent to do so, whereupon a written revocation of this consent is possible at any time.

5. Data have to be protected in an appropriate way against the access by unauthorised persons.

6. Obligations according to numbers 3 and 5 are also valid for persons who assist in the performance of genetic tests or the storage or administration of data collected thereby.

(2) As far as this act does not contain other provisions the data protection act 2000 – DSG 2000, BGBl. I Nr. 165/1999, the sanitary telematics act, BGBl. I Nr. 179/2004, as well as provisions containing special obligations of secrecy or to registration are valid.

### **Documentation of test results**

**Art. 71a.** (1) Results from genetic tests type 1 may be documented in discharge letters and medical histories in any case, results from genetic tests type 2 and 3 only if the patient did not object in writing. The possibility to object has to be pointed out in the course of genetic counselling according to art. 69 para. 3.

(2) Results from genetic tests type 4 as well as results from genetic tests type 2 and 3 where documentation in discharge letters and medical histories is illegitimate due to the patient's written objection, only may be automatically processed in that facility, where they have been collected and only by the instance of the attending physician; they have to be kept and to be stored separate from other types of data and only are allowed to be recalled by persons, who are directly involved with the collection, processing and evaluation of these data in the facility and only with a separate access option.

### **Authorisation for regulations**

**Art. 72.** (1) If it is required for the assurance of a troublefree performance of genetic tests and of genetic counselling being coherent therewith the federal minister of health and women has to prescribe provisions on the personal and functional equipment of a facility according to art. 68, including the qualification of the responsible laboratory manager according to art. 68a, the initiation of genetic tests according to art. 68 para. 1, the obligational information and counselling according to art. 69, data protection according to art. 71 and the documentation of test results according to art. 71a after hearing of the competent scientific advisory committee of the advisory board on biotechnology and genetic engineering, taking into consideration the respective scientific knowledge and technical progress.

(2) If, due to new scientific knowledge and technical progress, sufficient expert knowledge on the safety (art. 1 number 1) of specific genetic tests is available, the federal minister of health and women has, with regard to established methods and established indications, to define by regulation more detailed provisions on the use of consolidated regulatory procedures for

further applications for a facility being already approved according to art. 68 para. 3 after hearing of the competent scientific advisory committee of the advisory board on biotechnology and genetic engineering.

### **Obligations to report**

**Art. 73.** The head of a facility according to art. 68 has to report to the authority without delay all substantial changes of the functional and personal equipment of the approved facility with regard to the performance of genetic tests type 3 and 4, as well as - by using the therefor intended form - a summary on all genetic tests of type 3 and 4 having been performed in that facility for the year having expired respectively, starting with February 1<sup>st</sup> 2006.

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### **Compulsory Registry**

**Art. 79.** (1) The federal minister of health and women has to establish electronical registries, which comprise all

1. facilities performing genetic tests (registry for genetic tests)
2. somatic gene therapies on man (registry for gene therapy)
3. external quality assessment schemes being available (registry for external quality assessment schemes)

having been approved according to this act.

(2) The registry for genetic tests has to keep records on the name, address, homepage and the field of activity of the facility, the latter being structured after tests performed.

(3) The registry for gene therapy has to keep records on the name, address, homepage and the field of activity of the facility. The field of activity has to be specified by the titel of the clinical trial, the name of the trial manager and the indication. For each gene therapy used therapeutic genes and genetransfer systems as well as the course of the therapy and the final report have to be disclosed seperately in a part of the registry that is not open to the public.

(4) The federal minister of health and women has to transfer data according to para. 2 and 3 to the registries, taking into consideration possible changes due to obligations to report according to art. 73, para. 1 or art. 78a para. 1 (especially the course of the therapy and the final report), having to be included.

(5) All registries have to be updated continously.

(6) Published data may not contain any identifiable information on tested persons. The access to the registries has to be open for everyone. For the federal minister of health and women as well as the federal office for public health security – within the scope of their competence - also that part of the registry is accessible which is not open to the public.

### **Further provisions according to the Austrian gene technology act:**

The federal minister of health and women may publish a “gene technology book” (art. 99), consisting of different chapters, which shall document new scientific knowledge and technical progress for working with GMO, deliberate release of GMO and placing on the market of products thereof, as well as genetic testing and somatic gene therapy on man.

According to art. 101 bodies of the competent authority may inspect locations where it is assumed that genetic tests are being performed or data resulting thereof are automatically processed or stored and may look for the compliance with regulations of this act, examine protocols as well as take probes.

Penal regulations according to art. 109 envisage a fine for someone who

- demands, accepts or else makes use of results from genetic tests of employees, job applicants, insureds or insurance canvassers, contrary to provisions laid down in art. 67
- performs genetic tests for medical purposes in facilities not being approved or without meeting the conditions having been posed according to art. 65 and art. 68
- illegally performs genetic tests for scientific purposes or for education or publishes or networks data resulting from such tests contrary to provisions laid down in art. 66
- acts in opposition to the provisions of art. 68a on the obligate participation in external quality assessment schemes having to be organised by the laboratory manager and the obligate notification of a change of the laboratory manager to the competent authority by the head of the facility
- who initiates genetic tests without ensuring an informed consent according to art. 69 para. 1
- counteracts to provisions of art. 71 and art 71a on data protection and documentation of test results
- infringes provisions enacted according to art. 72 para. 1 on the equipment of a facility, the initiation of genetic tests, data protection or documentation of test results
- being the head of an approved facility, does not report all substantial changes of the equipment as well as a yearly summary of performed genetic tests type 3 and 4 to the competent authority, according to art. 73