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Legal Regulation for Genetic Testing in Austria

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- Introduction
- Austrian Gene Technology Act
- Administrative Procedure
- Austrian Book of Biotechnology
- Obligations to Report
- Inspections

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- **Introduction**

Molecular Genetic Testing on humans is regulated by the Austrian Gene Technology Act since 1995.

IV. section covers Genetic Testing and Gene Therapy on Humans.

In the light of almost 10 years of practical experience the relevant section on Genetic Testing was reviewed with Austrian experts to adjust the law to today‘s state of the art in Human Molecular Genetic Testing.

This amendment of the law came into force in 2005.

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Austrian Gene Technology Act

Definition of genetic testing according to Art. 4 (23) GTG:
Genetic testing is a 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 the state of the art of 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 humans.

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Austrian Gene Technology Act

Art. 65:

Genetic testing on humans for medical purposes is only allowed due to state of the art of scientific knowledge and technical progress. Genetic tests are classified into 4 types.

Type 1 serves the determination of a present 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.

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- **Austrian Gene Technology Act**

Type 2 serves the determination of a present disease, which is based on a germ line mutation.

Type 3 and 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 a prophylaxis or therapy is possible (Type 3) or not (Type 4).

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- **Austrian Gene Technology Act**

This classification is regarding to the potential consequences for the patient, where type 1 has the lowest potential impact.

The performance of genetic tests of type 3 and 4 is only allowed in therefore approved facilities and only on the inducement of a medical specialist trained in human genetics/medical genetics or of an attending or diagnosing medical specialist competent for the respective indication.

According to Art. 69 a genetic test of type 2, 3 or 4 is only allowed to be performed if there exists a written consent of the person to be tested, that this person has been informed in advance about the nature of the genetic test, the consequences and the significance of the genetic test.

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Genetic counselling:

Before and after a genetic test of type 2, 3, or 4 there has to be a detailed genetic counselling. This 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. The counselling is not allowed to be directive. The counselling has to be concluded with an individual counselling letter, which summarises the essential content in a generally understandable manner (Art. 69 GTG).

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- **Austrian Gene Technology Act**

Laboratory manager:
The head of the facility has to appoint one laboratory manager (LM).

The LM is responsible for the continuous instruction of co-workers, as well as the management and supervision 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.

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- **Austrian Gene Technology Act**

The needed qualification of the LM is laid down in the law.

The LM has to:

Be a medical specialist for human genetics/medical genetics or medical-chemical laboratory diagnostics, or

a medical specialist, including an education in human genetics/medical genetics and at least two years experience in MGT on humans, or

has to have an university degree in natural sciences, including education in molecular genetics or molecular biology and at least two years experience in MGT on humans.

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- **Austrian Gene Technology Act**

Art. 67: Prohibition of the collection and use of data from genetic tests for certain purposes:

Employers and insurers including authorised representatives and co-workers thereof are prohibited to collect, to demand, to accept ore else make use of results from genetic tests of their employees, job applicants or insuree or insurances canvassers.
This prohibition also covers the demand for delivery and the acceptance of body substances for genetic test purposes.

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Austrian Gene Technology Act

Further Articles regulating genetic testing:

Art. 66:
Genetic testing on humans for scientific purposes and for education

Main points:
Explicit informed consent is needed, or the specimen has to be anonymized.
A specimen is even considered to be anonymized, 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.

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- **Austrian Gene Technology Act**

Art. 70: Involvement of relatives

Art. 71: Data protection

Art. 71a: Documentation of test results

Art. 79 (1): Compulsory Register

The CA has to provide electronically registries which comprise all:

Facilities performing genetic tests (registry for genetic tests).

External quality assessment schemes being available (registry for external quality assessment schemes.

These registries are available on the homepage of the CA (www.gentechnik.gv.at).

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- **Administrative Procedure**

According to Art. 68 GTG the approval has to be applied at the Federal Ministry of Health by the head of the facility in which the performance of such genetic tests is intended.

The application will be checked to ensure that:

Personal and technical equipment, protection of the genetic data and intended genetic tests are state of the art.

This will be done by scientific officers at the ministry as well as by Austrian experts in the Scientific Committee of Genetic Testing and Gene Therapy (WAGG).

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- **Administrative Procedure**

Additional a inspection of the facility will be performed by the Competent Authority.

The approval will then be granted by the Minister of Health and if necessary appropriate conditions and requirements will be determined.

- **Austrian Book of Biotechnology**

Further regulations concerning genetic testing are laid down in the Austrian Book of Biotechnology (Gentechnikbuch).

It consists of chapters, which published if required.

It is published by the Advisory Board on Biotechnology.

It presents "state of the art" biotechnology.

It has a legal status of an objectified expert opinion.

Chapters can be published as an ordinance and thus enter into force like a law.

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- **Austrian Book of Biotechnology**

Relevant chapters for genetic testing are regulating in detail:

The state of the art performance of MGT and cytogenetic testing, based on international guidelines and the GTG.

Genetic Testing for pharmacogenetical purposes and a plan for the participation on external quality assessment schemes.

The Austrian Book of Biotechnology is available on the homepage of the CA (www.gentechnik.gv.at) (only in German).

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- **Obligations to Report**

According to Art. 73 GTG the head of the facility has to report to the CA:

Any substantial changes of the functional and personal equipment without delay.

An annual report on the performance of genetic tests of type 3 and 4 as well as the conformation of the successfully participation on the appropriate external quality assurance schemes.

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- **Inspections**

According to Art. 101 GTG the CA has the right to inspect facilities performing genetic testing.

These inspections are based on the provisions of the law as well as on the detailed check-lists published in the Austrian Book of Biotechnology.

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Thank you
for your
attention !