Legal provisions related to genetic testing in Germany

Act on Human Genetic Testing
*(Genetic Diagnosis Act; GenDG)*

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European Human Genetics Conference
WS10. Legal regulation for genetic testing
Gothenburg, 14.06.2010
Human Genetic Diagnostics

Quantitative changes
• Genes, mutations, polymorphisms
• New genetic tests (next generation sequencing, arrays)
• Availability of tests

Qualitative changes
• Role of genetics in medicine (Genomic Medicine)
• Prediction, prognosis, prevention
• Multifactorial diseases; pharmacogenomics
• Mass Screening
• Genetic knowledge in the general public
International Provisions

- Council of Europe – CDBI (Steering Committee on Bioethics)


- UNESCO

  „Universal Declaration on the Human Genome and Human Rights“ 1997

  „INTERNATIONAL DECLARATION ON HUMAN GENETIC DATA“ 2003

- + national provisions

  e.g. enquete-commission “Recht und Ethik der modernen Medizin” 2005
German GenDG

§1

The purpose of this Act is to determine the **requirements** for **genetic examinations** and **genetic analyses** conducted in the framework of genetic examinations and to **prevent** any **discrimination** and **disadvantage** based upon genetic characteristics, especially in regard to the duty of the state to **protect human dignity** and to ensure the individual **right to self-determination** via sufficient information.
German GenDG

§2 Scope of Application

This Act applies to genetic examinations and genetic analyses conducted within the framework of genetic examinations involving born natural persons as well as embryos and foetuses during pregnancy and the handling of genetic data and genetic samples gained thereby for medical purposes, for purposes of determining descent as well as in the insurance and employment sectors.
German GenDG

§2 Scope of Application

This Act does not apply to genetic examinations and genetic analyses or the handling of genetic samples or genetic data conducted

1. for research purposes,
2. on the basis of applicable regulations relating to
   a) criminal procedure, international legal assistance in criminal matters, the Federal Criminal Authority Act and the police laws of the several states, and
   b) the Infection Protection Act and the legal progeny of the Infection Protection Act.
German GenDG

General Provisions (Section 1)

§ 3 Definitions (*terms as genetic examination, genetic analysis, responsible medical person etc.*)

§ 4 Prohibition of Discrimination

§ 5 Quality Assurance of Genetic Analyses

§ 6 Restriction of Genetic Study Materials (*e.g. self readable tests*)
German GenDG

Genetic Examinations for Medical Purposes
Section 2

§ 7 Medical Doctor Reservations (genetic examination, counseling)

§ 8 Consent (expressed, written, informed)

§ 9 Duty to Inform (before consent)

§ 10 Genetic Counselling (predictive test: before and after the examination)

§ 11 Reporting the Results of Genetic Examinations & Analyses
(responsible medical person)
German GenDG

Genetic Examinations for Medical Purposes
Section 2

§12 Retention and Destruction of Results of Genetic Examinations and Analyses (10 years)

§ 13 Usage and Destruction of Genetic Samples (purpose, immed.)

§ 14 Genetic Examinations Involving Persons Lacking the Full Capacity to Consent

§ 15 Prenatal Genetic Examinations (late onset disease)

§ 16 Mass Genetic Screenings (GDC; new screenings; evaluate concept)
German GenDG

Section 3 Descent
§ 17 Genetic Examinations to Determine Descent (*informed consent, no secret testing allowed*)

Section 4 Genetic Examinations in the Insurance Sector
§ 18 Genetic Examinations and Analyses in Conjunction with the Conclusion of an Insurance Contract

Section 5 Genetic Examinations in the Workplace
§ 19 Genetic Examinations and Analyses before and after Formation of the Employment Relationship
§ 20 Genetic Examinations for Occupational Safety
§ 21 Labour Law Prohibition of Discrimination
§ 22 Public Servant Employment Relationships
German GenDG

Section 6 Generally Accepted Status of Science and Technology
§ 23 Guidelines (GDC)
§ 24 Fees and Expenses

Section 7 Sanctions and Fines
§ 25 Criminal Sanctions
§ 26 Fines

Section 8 Final Provisions
§ 27 Date of Commencement (effective date 1. Feb 2010)
Guidelines
Genetic Diagnostik Commission (GEKO)

- Independent, interdisciplinary Genetic Diagnostic Commission established at the RKI
- 13 experts: medicine and biology, 2 experts: law and ethics, as well as 3 representatives: patients, consumers, disabled persons
- Establishment of guidelines according § 23 GenDG
- Guidelines: in reference to the „generally accepted status of science and technology“
- Public statements; publication of guidelines
Robert Koch-Institut, Berlin, Germany

Thank you for your attention!
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