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Genetic Testing – An Overview of the New Provisions

1. What is at Issue?

On 1 December 2022, the revised Federal Act on Human Genetic Testing («Bundesgesetz über genetische Untersuchungen beim Menschen», **GUMG**), the Ordinance on Human Genetic Testing («Verordnung über genetische Untersuchungen beim Menschen», **GUMV**) and the Ordinance on DNA Profiling in the Civil and Administrative Field («Verordnung über die Erstellung von DNA-Profilen im Zivil- und im Verwaltungsbereich», **VDZV**) entered into force.

Scientific and technological advances in the field of genetic testing have made a total revision of the legislation on genetic testing necessary.

2. What Are the Most Important Changes?

(a) Application Also to Genetic Testing in a Non-Medical Context

The former legislation mainly regulated genetic testing in a medical context. Genetic testing for traits acquired in the course of life (e.g. many cancers) or in a non-medical context (e.g. genetic tests to clarify the athletic disposition or the affiliation to a primitive people such as Vikings or Celts) were not covered.

The revised legislation now regulates almost all kinds of genetic tests, including genetic tests in a non-medical context and genetic tests of non-hereditary traits (acquired traits that are not passed on to subsequent generations). However, excluded are e.g. genetic tests that are

regulated by the DNA Profiles Act or that fall within the scope of the Human Research Act.

(b) Strengthening of Personal Rights and Data Protection

The revised GUMG contains requirements that apply to all genetic testing, including the duty to provide comprehensive information before the person concerned consents («informed consent»), the «right not to know» the result, the avoidance of surplus information, requirements if samples and genetic data are to be used for other purposes and specific requirements for the protection of samples and genetic data (e.g. data security precautions).

Furthermore, depending on the consequences that possible misuse (e.g. unauthorized disclosure of genetic data) may have and depending on the need for protection of the persons concerned (e.g. young children), the various areas are regulated with varying degrees of strictness.

(c) Right to Prescribe Genetic Tests

As before, genetic tests in a medical context may primarily be prescribed by medical doctors. However, dentists, pharmacists and chiropractors can now also prescribe certain genetic tests in their respective area of expertise.

(d) Requirements for Laboratories Performing Genetic Testing

The laboratories performing the genetic tests are still subject to an authorization

requirement. However, they are now also subject to an accreditation requirement.

(e) Advertising for Genetic Testing

Advertising to the public for genetic tests in a medical context is generally prohibited. However, healthcare professionals (HCPs) who are authorized to prescribe such tests may, to a limited extent, engage in advertising. For genetic tests in a non-medical context (e.g. for the optimization of nutrition) and for the creation of DNA profiles (e.g. paternity tests), advertising to the public is permitted under certain conditions.

3. What Are the Various Categories of Genetic Tests and What Are the Respective Requirements?

In addition to the requirements that apply to all genetic testing (e.g. informed consent, right not to know, requirements for the protection of samples and genetic data etc.), the revised GUMG contains further requirements for the following categories of genetic tests:

(a) Genetic Tests in a Medical Context

Genetic tests in a medical context may only be **prescribed** by certain medical doctors in principle. In specific cases, dentists, pharmacists and chiropractors may also prescribe them.

These tests may only be performed after a personal **counselling** session and, if necessary (e.g. in the case of prenatal tests), detailed genetic counselling. The test result must be communicated to the person concerned by an HCP who will advise him or her if necessary.

In the case of young children and other persons **incapable of judgement**, genetic tests must have a current medical benefit.

Prenatal genetic tests may only examine whether the unborn child has health

problems. The sex may only be clarified if it serves to diagnose a disease. However, if the sex is determined during another clarification (e.g. non-invasive prenatal testing, NIPT), it is prohibited to inform the parents about it before the end of the 12th week of pregnancy.

(b) Genetic Tests in a Non-Medical Context

The revised GUMG differentiates between so-called «genetic tests on traits requiring special protection» and «other genetic tests»:

(i) Genetic Tests on Traits Requiring Special Protection

These tests include so-called **lifestyle genetic tests** (e.g. on athletic disposition, diet and weight, or personality) and genetic tests for **genealogical research**.

They may only be **prescribed** by HCPs, such as pharmacists, nutritionists and physiotherapists. The sample for the genetic test must be taken in the presence of the HCP to ensure that no secret tests are carried out on third parties and that no unauthorized tests are carried out on young children.

(ii) Other Genetic Tests («Direct-to-Consumer»)

These tests include relatively **harmless** tests, e.g. on the ability to perceive bitter taste or on the sneezing reflex when looking at the sun.

They do not have to be prescribed by an HCP and can thus be ordered directly by private individuals («direct-to-consumer» genetic testing).

The law does not impose quality requirements on laboratories that perform such tests.

(c) Paternity and Relationship Tests

The persons examined (e.g. father and child) must have **consented** to the test **in writing**. Accordingly, secret paternity tests are prohibited. If a child is not yet capable of judgment, someone must consent on behalf of the child. Since the father cannot represent the child in this matter, the mother's consent must usually be obtained.

The sample must be taken by an HCP. Since the result may have consequences under family law, the **identity** of the person tested must be verified before the test.

4. Overview of the Various Requirements

The Federal Office of Public Health (FOPH) has published a helpful overview of the various requirements¹:

Field Requirements	Medical (e.g. down syndrome, chorea huntington, cystic fibrosis)	Non-Medical		DNA Profiles (paternity tests)	Non-Hereditary Traits ² (e.g. cancer-causing changes, characteristics of a cancer, patterns of gene activity)
		Traits Requiring Special Protection (e.g. diet, athletic disposition, personality, geographical origin)	Other Traits (e.g. color of hair and eyes, sense of taste, consistency of ear wax)		
General requirements (e.g. informed consent, right not to know, protection of samples and genetic data etc.)	✓	✓	✓	✓	✓
Prescription by medical doctor or certain HCPs	✓	✓	✗	✗	—
Sampling under controlled conditions	✓	✓	✗	✓	—
Tests may be sold freely	✗	✗	✓	✗	—
Laboratory is subject to authorization or approval	✓	✓	✗	✓	✗
Communication of surplus information allowed	✓ ³	✗	✗	✗	✓ ⁴ ✗
Penal provisions	✓	✓	✓	✓	✓

✓: yes ✗: no —: not regulated

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¹ Cf. Table 2 on p. 7 of the document «Fragen und Antworten – Genetische Untersuchungen beim Menschen: Ein Überblick über die neuen Regeln» by the FOPH dated 1 December 2022; available at [bag.admin.ch > Gesetze & Bewilligungen > Gesetzgebung > Gesetzgebung Mensch & Gesundheit > Gesetzgebung Genetische Untersuchungen > Abgeschlossene Rechtsetzungsprojekte](http://bag.admin.ch/Gesetze_&_Bewilligungen/Gesetzgebung/Gesetzgebung_Mensch_&_Gesundheit/Gesetzgebung_Genetische_Untersuchungen/Abgeschlossene_Rechtsetzungsprojekte) (last visited on 12 December 2022).

² Not all listed provisions are applicable for the testing of non-hereditary traits.

³ When prescribed by HCPs other than medical doctors, the communication of surplus information is not permitted.

⁴ In a medical context, the person concerned decides what information should be communicated to him/her. In a non-medical context, the communication of surplus information is prohibited.