This information sheet has been drawn up jointly by the Swiss Agency for Therapeutic Products, Swissmedic, and the Swiss Federal Office of Public Health (FOPH). It provides guidance on the regulation of genetic tests as products for detecting characteristics of the human genome.

1 Legal basis

Genetic tests can be carried out for medical or non-medical purposes. If the purpose is a medical one, the products used are regulated as medical devices by the Therapeutic Products Act (TPA). Products for non-medical tests are not, however, regulated by the TPA. The conducting of genetic tests for the medical sector and also for the employment, liability and insurance sectors is regulated by the Federal Act on Human Genetic Testing (HGTA). The HGTA also regulates the creation of DNA profiles for the purpose of determining the filiation or identity of an individual. The DNA Profiling Act applies to the use of DNA profiles in criminal proceedings and for the purpose of identifying unknown or missing persons.

2 Terminology

In accordance with Article 3, letter a, HGTA, "genetic analysis" means cytogenetic and molecular genetic analysis to determine hereditary characteristics of human genetic material or characteristics of human genetic material acquired during the embryonic phase, and all other laboratory tests whose immediate purpose is to provide such information about genetic material.

The term "genetic test" used in this information sheet also encompasses genetic tests that are carried out in a medical context but that are not subject to the HGTA. This includes, for example, the genetic investigation of a tumour disease for which the underlying mutations are not hereditary or acquired during the embryonic phase but have occurred during the person's life (somatic mutations).

3 Genetic tests as medical devices

As kits, reagents, control or calibration materials, analytical systems and apparatus, including the related software, genetics tests are in-vitro diagnostic medical devices (IVDs) if they are used for in-vitro analysis of samples taken from the human body and if they serve a medical purpose, i.e. if they serve to:

- provide information on physiological or pathological conditions, or
- on inherited anomalies, or
- are used to test safety and tolerability in potential recipients, or
- to monitor therapeutic measures.

Examples of IVDs are genetic tests for haemochromatosis (HFE gene mutations), haemostasis disorders (Factor V disorder), genetic tests to define tissue types (HLA typing), pharmacogenetic tests (e.g. CYP450 system) or genetic tests on chromosome disorders whose results can be taken into consideration for therapies, medical care or medical interventions.

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1 Genetic tests on animals and micro-organisms are not addressed in this information sheet
2 Federal act on Medicinal Products and Medical Devices (Therapeutic Products Act, TPA; Heilmittelgesetz HMG), SR 812.21
3 Federal Act on Human Genetic Testing (HGTA), Bundesgesetz über genetische Untersuchungen beim Menschen (GUMG), SR 810.12
4 Federal act on the Use of DNA profiles in Criminal Proceedings and for the Purpose of Identifying Unknown or Missing Persons (DNA Profiling Act), Bundesgesetz über die Verwendung von DNA-Profilen im Strafverfahren und zur Identifizierung von unbekannten oder vermissten Personen (DNA-Profil-Gesetz), SR 363
Paternity tests to determine filiation or creation of DNA profiles for identification or for use in criminology are not IVDs since their purpose is not medical.

Legal provisions regulating genetic tests as medical devices:

a. As IVDs, genetic tests must satisfy the technical and regulatory requirements set out in European Directive 98/79/EC on in-vitro diagnostic medical devices (IVD Directive), which has been implemented in Switzerland by means of the TPA and the Medical Devices Ordinance (MedDO)\(^5\).

b. Annex I of the IVD Directive describes the essential requirements to be fulfilled by the IVDs before they may be placed on the market. Annexes III – VII of the Directive describe the conformity assessment procedures that must be completed by manufacturers of IVDs. IVDs must carry a clearly visible CE marking to indicate their conformity with the IVD Directive. Laboratories in Switzerland that develop their own IVDs for medical analytics (in-house IVDs), are also considered to be placing the said IVDs on the market and must fulfil the requirements set out in the TPA and the MedDO.

\(^5\) Medical Devices Ordinance (Medizinprodukteverordnung, MedDO), SR 812.213
Swissmedic is the authority responsible for enforcing the TPA and MedDO, which also includes European IVD Directive 98/79/EC. The Agency is responsible for the surveillance of IVDs that are on the market (Sections 5 to 7 MedDO), and for that purpose exchanges information with foreign authorities (Article 64 TPA). It records the mandatory notifications of IVDs that are placed on the market by manufacturers or authorised representatives located in Switzerland (Article 6 MedDO). Those placing IVDs on the market and professional users of IVDs must report adverse events involving IVDs to Swissmedic (Article 15 MedDO). Those placing IVDs on the market must also report recalls and other safety measures to Swissmedic (Article 15 MedDO). This information enables Swissmedic to check the conformity of individual devices and companies and take measures within the framework of market surveillance.

The FOPH is responsible for enforcing the HGTA and the Human Genetic Testing Ordinance (HGTO), for approving medical laboratories, and for all questions relating to the reimbursement of costs for genetic tests that are covered by compulsory basic healthcare insurance. Within the framework of this enforcement, and in accordance with Articles 12 and 13 of the HGTO, periodic laboratory inspections are carried out. Controls of accredited laboratories take place within the framework of the annual audits carried out by the Swiss Accreditation Service SAS. The other laboratories are regularly inspected by Swissmedic on behalf of the FOPH.

The Cantons are responsible for ensuring that independent information and advisory centres for prenatal tests are available and are staffed by the required specialists.

6 Tests abroad

Swissmedic and the FOPH cannot approve foreign laboratories, supervise them, or monitor the in-house tests used there. In accordance with Art. 21 HGTO, cytogenetic and molecular genetic tests may only be transferred to a foreign laboratory if it is guaranteed that the laboratory in question uses state-of-the-art scientific and technical methods. If a laboratory accredited by the FOPH sub-contracts a test to a foreign laboratory, it must prove to the FOPH, on request, that it has obtained the relevant information regarding the said laboratory. If a medical doctor who has prescribed a genetic test in Switzerland uses a foreign laboratory to directly carry out the test, the doctor must have obtained the relevant information about the laboratory in advance.
7 Contacts

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Further information on medical devices and IVDs is available on the Swissmedic website at www.swissmedic.ch/md

Further information on genetic tests in humans is available on the FOPH website (in German, French and Italian), at www.bag.admin.ch/genetictesting

Information on health insurance coverage for genetic tests can be found in German, French and Italian on the list of tests on the FOPH website (Analysenliste, see www.bag.admin.ch/al)

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