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].

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)*[2]. 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)*[3]. 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[4].

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.

[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

Swissmedic • Hallerstrasse 7 • CH-3000 Bern 9 • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

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.

c. Further requirements are summarised in a Guide to the regulation of medical devices, available at www.swissmedic.ch/md). For laboratories, an information sheet on in-house IVDs is available at (www.swissmedic.ch/md > "Market access" > "Notification of IVD medical devices")

4 Other provisions for genetic tests in accordance with the HGTA

Genetic analyses in the medical context may only be prescribed by medical doctors. The persons concerned must also have freely provided their consent after receiving sufficient information. Consent must be given in writing for presymptomatic and prenatal genetic tests and genetic tests for family planning (clarification of any genetic risk for future offspring). When the results of the analysis are available, the persons concerned are, in addition, free to decide whether they wish to be informed of them ("Right not to know"). Presymptomatic and prenatal genetic tests and tests for family planning must be accompanied, prior to and after the tests, by non-directive, expert genetic counselling. Future parents may also approach the Cantonal Information and Advisory Centres with regard to prenatal tests.

In Switzerland, genetic analyses may only be carried out in medical laboratories duly approved by the FOPH (for tests in other countries, see below). The requirement for approval, which is granted if certain criteria are fulfilled, and the supervision of the laboratories by the FOPH are aspects that ensure a high quality standard for conducting the tests and interpreting the results.

The dispensing of in-vitro diagnostic genetic tests to individuals for a purpose that is not related to their trade or profession is forbidden.

5 Responsibilities

In contrast to the situation regarding medicinal products, Swiss authorities are not responsible for authorising IVDs or other medical devices on the market. Medical devices are subject to European requirements and conformity assessment procedures. These are recognised in all EU Member States, EFTA States (including Switzerland) and in Turkey. Swissmedic does not, therefore, issue any official authorisations for IVDs, nor does it have any systematic documentation on the individual products.

[5] Medical Devices Ordinance (Medizinprodukteverordnung, MedDO), SR 812.213

Swissmedic • Hallerstrasse 7 • CH-3000 Bern 9 • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

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.

Swissmedic • Hallerstrasse 7 • CH-3000 Bern 9 • www.swissmedic.ch • Tel. +41 58 462 02 11 • Fax +41 58 462 02 12

7 Contacts

Swissmedic
Swiss Agency for Therapeutic Products
Medical Devices Department
Hallerstrasse 7, Postfach
CH-3000 Bern 9
Phone: +41 (0)58 463 22 51
Fax: +41 (0)58 462 76 46
E-mail medical.devices@swissmedic.ch

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

FOPH
Federal Office of Public Health
Department of Biomedicine
Genetic Testing
CH-3003 Bern
Phone: +41 (0)31 323 51 54
Fax: +41 (0)31 322 62 33
E-mail genetictesting@bag.admin.ch

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)

Change history

Version	Valid and binding as of:	Modified without version change	Description, comments (by author)	Author's initials
02	**01.01.2017**		**List of contents removed**	**wkn**
01	**21.10.2016**		**Revision of stakeholder details, semantic clarifications and first inclusion in QM / old document name: Information Sheet on Genetic Tests**	**ans**