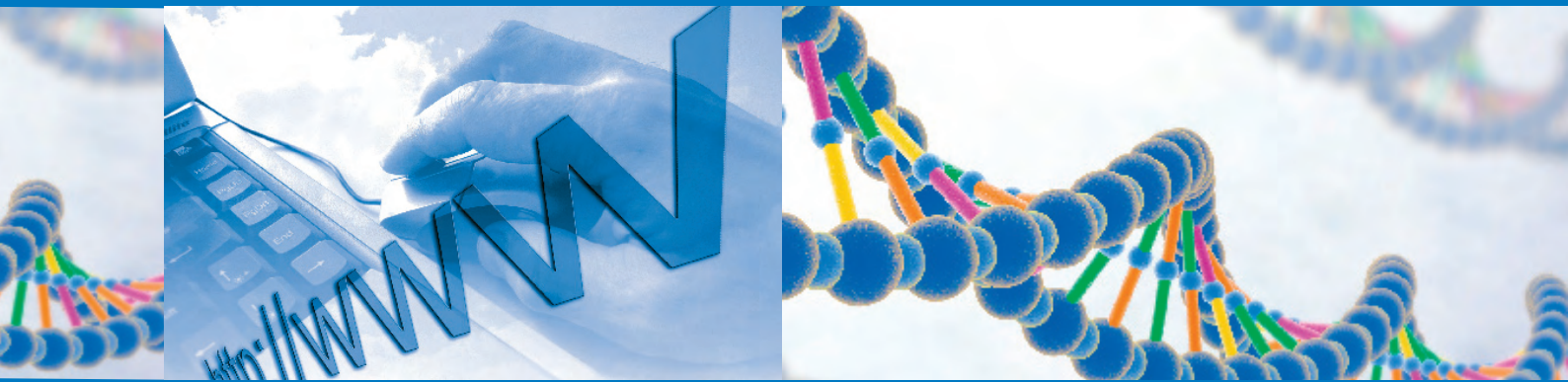




Recommendations of the Expert Commission on Human Genetic Testing (ECHGT)

Internet-based genetic testing

A number of foreign companies offer genetic tests over the Internet. They claim to provide information on a wide variety of disease risks for consumers who send in a saliva sample. DNA analyses are difficult to carry out and interpret, and the results may have far reaching consequences for test subjects and their relatives.

The Expert Commission on Human Genetic Testing (ECHGT) considers the provision of genetic tests on the Internet to be problematic and fraught with risks. It therefore advises consumers against using such services and recommends addressing questions concerning genetic testing to a healthcare professional (physician or pharmacist).

Why are genetic tests performed?

In medical practice, genetic tests are mainly used in the following situations:

- **Uncertain diagnosis:** A suspected genetic disorder is confirmed or excluded with the aid of a genetic test. The results may be important for the choice of treatment.
- **Prenatal testing:** A genetic test shows whether an unborn child has a given genetic disorder.
- **Family planning:** In genetic counselling, the risk of disease in offspring is investigated.
- **Family history of genetic disease:** In patients' relatives, the predisposition to the disease in question is assessed before any symptoms become apparent (presymptomatic testing).

The tests offered on the Internet are generally designed to assess whether a person is at an increased risk for certain common conditions (e.g. hypertension, diabetes, heart attack). To this end, a computer scans a small fraction of a person's genome (which contains more than 20,000 genes) for minor variations – so-called single nucleotide polymorphisms (SNPs). Some of these SNPs occur more frequently in people who suffer from certain diseases. These small variations are therefore assumed to play a role in the development of these diseases. However, they are never the only factor causing disease.

For medical research, such findings are extremely important in helping to improve our understanding of disease processes and to develop novel treatments. For individuals, however, the tests are not sufficiently meaningful.

In the current state of knowledge, the results of such tests cannot yield any conclusions concerning a person's risk of disease or individual recommendations (e.g. diet).

No genetic tests without genetic counselling

When genetic testing is offered over the Internet, test subjects are left to cope by themselves with predictions concerning their risk of developing dozens of severe, sometimes life threatening diseases. The results may give rise to anxieties which the person concerned can scarcely deal with in the absence of appropriate counselling and care. Conversely, a «normal» finding may provide a false sense of security, leading people to neglect effective preventive or therapeutic measures.

As genetic tests can have major impacts on test subjects and their relatives, it is important to discuss the question in advance with a healthcare professional (physician or pharmacist). If the need for such a test is confirmed, it is advisable to consult a medical specialist, who will order the test and ensure that the subject receives individual genetic counselling. This will take into consideration both clinical data (e.g. blood pressure or blood sugar measurements) and the medical history of the test subject and family members. Predictions generated automatically by a computer and communicated via the Internet are no substitute for personal counselling of this kind.

Accordingly, anonymous risk profiles that consider genetic risk factors exclusively – as is typically the case with Internet-based services – are regarded by the ECHGT as unprofessional and misleading.

Quality and safety of genetic tests

Performing genetic tests and interpreting the results are highly demanding tasks. Dealing with the results poses major challenges both for those who carry out the tests and for the people concerned. For this reason, in Switzerland and many other countries, genetic testing is subject to stringent regulations, e.g. concerning the qualifications of the physicians ordering such tests, quality requirements for laboratories and genetic counselling.

In contrast, the genetic tests offered on the Internet are not regulated by any authority – either in the country where the company is based or in the country from which it receives orders for tests.

In Switzerland, laboratories are only permitted to use genetic material to carry out analyses that have been specifically requested by a physician and to which the subject has consented. Only this person and his or her physician will be informed of the results. Online providers, however, can use a sample to study additional genes. They thus acquire more information than the physician, without being bound by a duty to maintain confidentiality. The test subject has no way of ensuring that the provider does not – either immediately or at a later date – perform analyses other than those advertised on the Internet.

The ECHGT, the Swiss Medical Association, the Swiss Pharmacists' Association, the Swiss National Advisory Commission on Biomedical Ethics, the Swiss Society of Medical Genetics, the Swiss Union for Laboratory Medicine and the Swiss Society for Public Health therefore recommend that consumers do not use such Internet-based testing services.

Data protection with genetic tests

In Switzerland, the Federal Act on Data Protection regulates the handling of personal data, thereby protecting privacy. Professionals who analyse patients' genetic material in this country comply with stringent regulations concerning the handling of the sample and test results and the storage of data.

All EU member states ensure appropriate data protection, comparable to that provided for under Swiss law. In many other countries, however – including countries where numerous online testing services are based – data protection does not meet the Swiss requirements.

No Internet-based tests for children

Internet-based genetic tests are particularly problematic in the case of children.

In Switzerland, genetic analyses can only be performed with the consent of the person concerned. The law protects people who lack legal capacity, including children. Genetic tests involving children are only permissible if they are necessary to protect the subjects' health.

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