

Revision of the Regulation on Genetic Testing

The Initiation and Performance of Genetic Tests

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Abstract: This article provides insights in the future set-up of genetic tests by physicians and non-physicians. The revised Federal Act on Human Genetic Testing will cover genetic tests inside and outside the medical field. The initiation and performance of such genetic tests are regulated by the respective Ordinance. Dentists, for example, will be allowed to order certain pharmacogenetic and diagnostic genetic tests in the field of dentistry. The new Ordinance will also regulate in particular the “direct-to-consumer genetic tests”, which are already widely offered on the Internet today.

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I. Keeping up with Scientific Developments

The existing Federal Act on Human Genetic Testing (GUMG) only came into force twelve years ago. In the meantime, it has been realised that this law is already outdated and can no longer keep pace with scientific developments.¹ The scope of the revised Federal Act

on Human Genetic Testing (nGUMG) has been considerably extended in two points.² The law now also covers non-heritable traits and regulates genetic testing outside the medical field.³ Genetic tests outside the medical field, so-called lifestyle tests, are already available in pharmacies, drugstores and also on the internet without being regulated by the current law. This non-medical area is categorised according to properties worthy of protection and other properties. In the medical field, the nGUMG in particular takes into account the fact that genetic tests have become much faster, cheaper and more effective. Today, genetic tests already make it possible to issue numerous statements about physiological characteristics, intelligence development indicators and predispositions of a person. In summary, genetic tests can now be divided into three categories: (a) Genetic tests in the “medical field” (“medizinischer Bereich”) and genetic tests outside the medical field with the subcategories (b) tests concerning “properties worthy of protection” (“schützenswerte Eigenschaften”) and (c) tests concerning “other properties” (“übrige Eigenschaften”).

The comprehensive regulation of genetic testing by the nGUMG ensures that even newly developed genetic tests, for example, tests in which several genes are examined simultaneously (multigene panel testing), are subject to legal regulation. The nGUMG gives the Federal Council the necessary flexibility in order to adapt the requirements for genetic testing to new developments.⁴

The nGUMG is complemented by ordinances, which concretise the legal provisions. One ordinance to be adapted is the Ordinance on Genetic Testing of Human (revGUMV). In particular, the revGUMV deals with the initiation of genetic tests in the medical field by physicians (sect. II), the definition of health care professionals who may initiate genetic

² A detailed discussion can be found in SCHOTT MARKUS/MAYORAZ JEAN-FRANÇOIS, Totalrevision des Bundesgesetzes über genetische Untersuchungen beim Menschen, in: LSR 2018, 267.

³ See Federal Department of Home Affairs (FDHA), Explanatory notes on the total revision of the Ordinance on Genetic Testing of Human Beings (GUMV), May 2020, p. 5 et seq.

⁴ As a consequence of the amendments to the GUMG, the relevant ordinance law must also be adapted. This consists of the following ordinances: (i) Ordinance of 14 February 2007 on genetic testing of humans (revGUMV), (ii) Ordinance of the FDHA of 14 February 2007 on genetic testing of humans (revGUMV-EDI) and (iii) Ordinance of 14 February 2007 on the preparation of DNA profiles in civil and administrative matters (revVDZV).

¹ See Dispatch of 5 July 2017, BBI 2017 5597 seq., p. 5598.

