Portugal’s “Genetic Information Law” (Law 12/2005, 26 Jan.)

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“Personal Genetic Information and Health Information”

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Scope

- Protection of genetic information
- Genetic testing in health-care
- Genetic counselling
- Genetic databases and biobanks
- Biomedical research and health care
- Non-discrimination measures
**Health information**, any information directly or indirectly linked to the present or future health status of any person, either living or deceased, including the clinical and family history

**Medical information**, the health information intended to be used for provision of health care and treatment
Genetic information, the health information associated to hereditary characteristics of one or more persons biologically related (identity and forensic genetic testing, but also somatic mutations, are excluded, for the purposes of this Law) obtained through any means, including molecular genetics, cytogenetics, biochemical genetics, physiological or imagiological tests, and pedigree information.
**Genetic information** is considered to be medical in nature only when used for the confirmation or exclusion of a clinical diagnosis, in prenatal or preimplantation diagnosis or for pharmacogenetics purposes, thus excluding presymptomatic and susceptibility testing.

**Types of genetics tests** (Dx, carrier, PST, susceptibility, PhG, PND, PGD, screening)
Genetic database, any register, either in an informatics support or not, containing genetic information on a group of persons or families

If a database or a genetic registry includes any kind of family information it must be kept and curated by a medical geneticist
Biobank, any collection of biological samples or its derivatives, previously or prospectively collected, obtained through health care provision, population screening, or research, either with or without identification, and with or without a time limit.
Health information is the property of the person to whom it pertains (though access to it is made through an authorized physician) and cannot be used for any aims other than health care and health research, or others defined by law.
Only information of **immediate interest for the patient’s current health** (diagnostic and pharmacogenetic information) can be entered in general hospital records.

Predictive information from carrier, presymptomatic, susceptibility, prenatal or preimplantation tests can only be kept in records of genetic services that keep separate files.
Genetic counselling

• Diagnostic or pharmacogenetic testing should follow the general principles of any other health care provision.

• Carrier, presymptomatic and susceptibility testing must be preceded by genetic counselling and written informed consent, and requested by a medical geneticist.

• Counselling should be proportionate to the severity of the disease, usual age at onset and existing treatment.
• In severe, late-onset disease with no effective treatment, predictive tests must be preceded by a psychosocial evaluation and follow-up after delivery of results

• Presymptomatic/predictive testing and PGD should only be performed in persons that can fully appreciate all its implications and give their informed consent
Government should regulate the offer of genetic testing, to avoid direct marketing to the public, by public or private lab, out of the context of genetic counselling

- Licensing, certification and accreditation

- Professionals employed by insurers, employers or any goods and service providers are not exempt from their confidentiality duty regarding their patients
• **Insurers** cannot ask for a genetic test or use test results or any other kind of genetic information already available, including family history, to refuse insurance or establish higher premiums.
Employers cannot select or ask their current employees’ for genetic tests or previous test results, **even with their own consent**, except for their health or safety **protection** (e.g., hazardous environments), and only if done in the context of genetic counselling and if employment is not put at stake; …
• the exception could be made in case of serious risk to public safety or public health, in which case genetic testing must be conducted by an independent entity
• No genetic testing or any kind of genetic information can be requested in case of adoption, both to the adoptees or the prospective parents.
In the case of minors, genetic testing should be done only for their benefit, after written consent from their parents or legal tutors, but always seeking to obtain the minors assent...
In case of severe, uncurable diseases, with onset usually in adult life, presymptomatic testing cannot be performed in minors.

And prenatal testing should not be done just for information of the parents but only with the aim to prevent the birth of an affected child (TOP up to 24 weeks).
• In case of genetic screening, the rights of the population or population groups should also be protected, in addition to their individual rights.
• Collection, conservation and usage of biological samples for genetic testing should be subject to an informed consent separate for health care and biomedical research, including its purposes and duration of storage
Commercial use

- Biological samples cannot be used for any commercial purposes
- Commercial entities cannot store or use identified or identifiable samples
- If absolutely needed, coded samples can be used, if the identifying codes are kept at a public institution
If consent for a different purpose cannot be obtained, e.g. in case of death, stored samples can be used in the context of genetic counselling, in order to enable treatment or the prevention of a genetic disease in a relative (but not to know the genetic status of other family members).
• If consent is not possible (proband deceased) or easily obtainable (e.g. large amount of samples needed), samples can be used for family studies, or can be processed for epidemiological or statistical purposes, only if previously and irreversibly anonymised.
A biobank must have a health care or a (basic or applied) health research purpose. If communication of results can be foreseen, a medical geneticist should be involved. Previous authorization must be requested from the health authorities and, in case of identified or identifiable samples, from the national personal data protection agency.
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Decreto n.º __________

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A Lei n.º 12/2005, de 26 de Janeiro, veio definir o conceito de informação de saúde e de informação genética, a circulação de informação e a intervenção sobre o genoma humano no sistema de saúde, bem como as regras para a colheita e conservação de produtos biológicos para efeitos de testes genéticos ou de investigação.

É em regulação dessa lei que o presente decreto-lei estabelece os princípios inerentes à realização e disponibilização de testes genéticos, prevendo igualmente as regras de protecção da informação genética, em termos de acesso, segurança, confidencialidade e sigilo dos dados. São, assim, regulamentados o n.º 6 do artigo 6.º, o n.º 2 do artigo 7.º, o n.º 1 do artigo 15.º, e o n.º 7 do artigo 17.º da Lei n.º 12/2005, de 26 de Janeiro.

Regulation of Law 12/2005 is still waiting…!