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Direct-to-Consumer Genetic Testing: the European regulatory landscape

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Talk Outline

- Timeline of offer and normative documents
- National legislation
- Europe wide initiatives
 - Additional protocol
 - IVD directive
- Latest updates of normative documents
 - Human Genetics Commission
 - ESHG
- Public Awareness Initiatives
- Food for thought



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DTC GT is not new





Normative documents DTC GT

Year	Organization	Document title
1997	Advisory Committee on Genetic Testing (ACGT), UK	<i>Code of Practice and Guidance on Human Genetic Testing Services Supplied Direct to the Public</i>
2003	Human Genetics Commission (HGC) / United Kingdom	<i>Genes direct. Ensuring the Effective Oversight of Genetic Tests Supplied Directly to the Public</i>
2004	Belgian Advisory Committee on Bioethics (BACB) / Belgium	<i>Opinion no. 32 of 5 July 2004 on the Free Availability of Genetic Tests</i>
2004	National Consultative Ethics Committee for Health and Life Sciences (NCEC) / France	<i>Opinion no. 86 – Problems connected to marketing self-test kits for HIV Screening and Diagnosis of Genetic Disease</i>



Timeline: normative documents

DTC GT

Year	Organization	Document title
2007	Human Genetics Commission UK	<i>More Genes Direct. A Report on Developments in the Availability, Marketing and Regulation of Genetic Tests Supplied Directly to the Public</i>
2008	National Council of Ethics for the Life Sciences (NCELS) / Portugal	<i>Opinion no. 56 of the National Council of Ethics for the Life Sciences – Opinion on Direct Marketing of Genetic Tests to the Public</i>
2009	Swiss Society of Medical Genetics (SSMG) / Switzerland	<i>Tests génétiques sur Internet</i>



Timeline: normative documents

DTC GT

Year	Organization	Document title
2009	Human Genetics Commission UK	DRAFT of A common framework of Principles for direct-to-consumer genetic testing services
2010	European Society of Human Genetics	ESHG statement on direct-to-consumer genetic testing for health purposes



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Existing National Legislation

-that control offer of DTC GTs





Regulating: how? Who? areas?

- Regulation does not mean banning
- Different actors can be involved
- Different areas can be controlled
 - Test quality (through IVD directive)
 - Advertising
 - Contracts
 - **Provision of medical services**
 - E-health



DTC GT banned by law in some European Countries

- Switzerland
- Germany
- France
- Portugal ?
- Austria ?



Swiss Law (2007)

Loi fédéral sur l'analyse génétique humaine (810.12) (2007)

Section 3, article 13: Droit de prescrire une analyse génétique

1 “Une analyse génétique ne peut être prescrite que par un médecin habilité à exercer à titre indépendant ou sous la surveillance d'un tel médecin.”

... 2 formation posgrade pour les analyses présymptomatique, prénatale ou pour planning familial

...3 besoin de conseil génétique



German Law (2009)

- **Genetic Examinations for Medical Purposes Section 2**
- § 7 Medical Doctor Reservations (*genetic examination, counseling*)
- § 10 Genetic Counselling (*predictive test: before and after the examination*)



Portuguese Law

- Portuguese Law 12/2005 (26 February 2005)
- Carrier, presymptomatic and susceptibility testing should be preceded by genetic counselling and written informed consent, and requested through a medical geneticist



Austria, law GC

- Austrian Gene Technology Act – Gentechnikgesetz, BGBl. Nr. 510/1994. According to § 69,
- non-directive genetic counselling is mandatory before and after genetic testing. Counselling shall cover medical facts, test results as well as social and psychological consequences. The rule concerns both predictive and carrier (post- and prenatal) genetic testing.



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Europe wide initiatives

- additional protocol
- IVD directive





Europe wide initiatives

Council of Europe : Additional protocol to the Convention on Human Rights and Biomedicine concerning genetic testing for health purposes. 2008



European Convention

- **Framework treaty with leading principles**
- **Article 12 – Predictive genetic tests**

Tests which are predictive of genetic diseases or which serve either to identify the subject as a carrier of a gene responsible for a disease or to detect a genetic predisposition or susceptibility to a disease may be performed only for health purposes or for scientific research linked to health purposes, **and subject to appropriate genetic counselling.**



Additional protocol

- **Article 5 – Quality of genetic services**
- genetic tests should meet “generally accepted criteria of scientific validity and clinical validity”



Additional protocol

- **Article 6 – Clinical utility**
- Art. 6. “Clinical utility of a genetic tests shall be an essential criterion for deciding to offer this test to a person or a group of persons”



Additional protocol

- **Article 7 – Individualised supervision**
- Art. 7.1 “A genetic test for health purposes may only be performed under individualised medical supervision.”
- Art. 7.2. “**Exceptions** to the general rule referred to in paragraph 1 may be allowed by a Party, subject to appropriate measures being provided, taking into account the way the test will be carried out, to give effect to the other provisions of this Protocol.”



Additional protocol

- However, such an exception may not be made with regard to genetic tests with important implications for the health of the persons concerned or members of their family or with important implications concerning procreation choices.



Additional protocol

- Draft Explanatory Report:
 - Purpose: “to define and safeguard fundamental rights of the persons concerned by genetic testing for health purposes.”
 - 64. Reg. Art. 7. “driven by the concern to enable the person concerned to have **suitable preliminary information with a view to an informed decision** regarding the carrying out of this test and, if appropriate, to have access to an appropriate genetic counselling. **A precise evaluation of the situation of the person concerned, involving direct contact with him or her, is a determining element in that respect. A mere telephone conversation with a medical doctor, for example, does not allow for such evaluation.**””



Additional protocol

- **Article 8 – Information and genetic counselling**
“ When a genetic test is envisaged, the person concerned shall be provided with prior appropriate information in particular on the purpose and the nature of the test, as well as the implications of its results.”



Additional protocol

- Signatures and ratification
- Application/ exceptions



IVD directive “101”

In-Vitro Medical Devices Directive (98/79/EC)

“Any medical device that is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus equipment, or system, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information: Concerning a physiological or pathological state, or concerning congenital abnormality, or to determine the safety and compatibility with potential recipients, or to monitor therapeutic measures.”



IVD directive purpose

- is to ensure that only safe and functional products are sold in the European market, with clearly outlined regulations regarding manufacture, importing, and marketing.
- Since Dec 2003 IVD products offered for sale in EU member countries were required to conform to IVD Directive requirements and to be IVD CE marked.



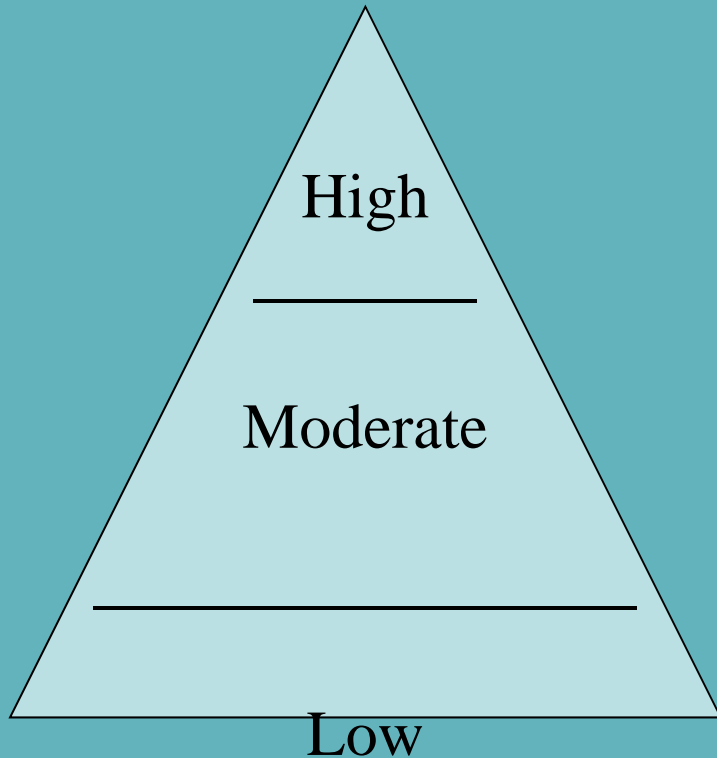
In-Vitro Medical Devices Directive

- Content IVD-directive
 - Scope and definitions
 - Placing product into the market: essential requirements
 - Risk categories
 - Conformity assessment procedures
 - Registration responsibilities
 - ...

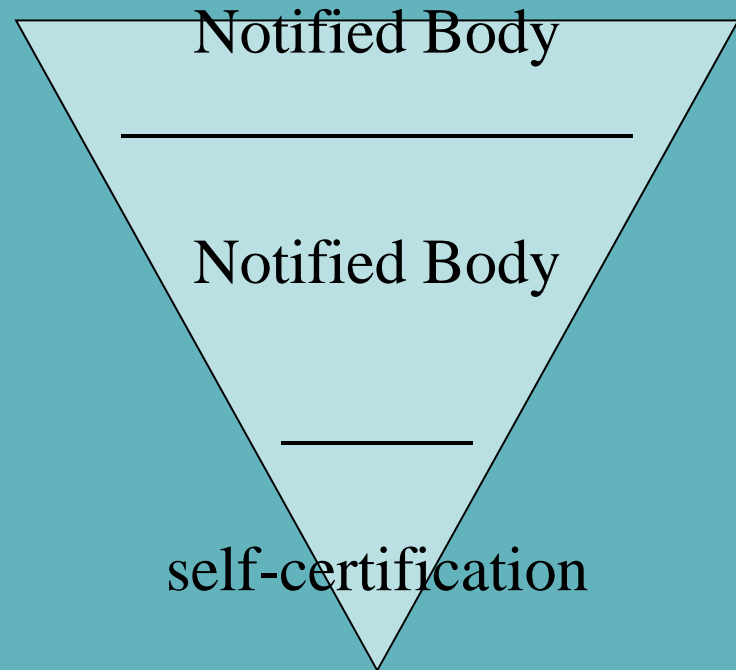


Risk classification

Risk category



Control





Latest normative documents

- Common Framework of Principles
- ESHG Statement





Human
Genetics
Commission

December 2009

A Common Framework of Principles for direct-to-consumer genetic testing services

Principles and Consultation Questions



HGC Principles

- Drafted by many stakeholders
- Goal: to promote good practice guidelines
 - at an international level
 - to protect the interests of consumers



HGC Principles

- **Marketing and advertising** – comply with legislation
 - Honesty in advertising
- Regulatory Information
- **Information for prospective consumers** - should be adequate re: test, research, data protection
- Consent
- Data protection Sample handling
- Laboratory processes



HGC Principles

- Interpretation of test results
 - Interpretation of genetic test results should be carried out under the responsibility of an appropriately qualified professional
 - genetic test results is accurate and take steps to ensure that these results are comprehensible to the consumer.
- Provision of results
 - In particular, the test provider should consider whether the test results should be provided only in the context of a consultation with a suitably qualified genetics health professional, and make provision accordingly.
- Continuing support
- Complaints



Professional and Public Policy Committee of the ESHG



European Society of Human Genetics - ESHG

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ESHG Committees and Subcommittees

Below an overview of the standing committees of the ESHG:

- [Ad-hoc Committee for the Accreditation for Clinical/Medical Geneticists](#)
- [Ad-hoc Committee for Accreditation of Genetic Nurses/Counsellors](#)
- [Ad-hoc Committee for the Accreditation for Laboratory Geneticists](#)
- [Annual Meetings Committee \(AMC\)](#)
- [Communications Committee](#)
- [Education Committee \(EC\)](#)
- [Genetics Services Quality Committee \(GSQC\)](#)
- [Professional and Public Policy Committee \(PPPC\)](#)
- [Publication Committee](#)
- [Scientific Programme Committee \(SPC\)](#)



DTC genetic testing for health-related purposes

- Right to genetic information
- DTC advertising of genetic testing
- **Quality of genetic testing services**
 - The quality of the tests (in terms of their analytical validity, clinical validity and utility)
 - The quality assurance of the laboratories
 - Proper qualifications, training and education of the personnel involved



DTC genetic testing for health-related purposes

- **Individualized medical supervision**

- The offer of genetic tests providing health-related information, in the absence of clinical indications and individualised medical supervision, may compromise patient health.

Pre-test information and genetic counselling

- A website cannot replace appropriate pre-test and post-test genetic counseling, which involves a face-to-face consultation with a knowledgeable professional.
- conflict of interest



DTC genetic testing for health-related purposes

- Informed consent
- Genetic testing in minors
- Respect for private life
- Research
- Oversight of genetic testing
- Impact on the healthcare system



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Public Awareness Campaign

- EuroGentest
- Genetics Interest Group





Increase Public Awareness

EuroGenetest HARMONIZING GENETIC TESTING ACROSS EUROPE

Home Medical Professionals Laboratories Students Patients & Family Industry About Us Documents Events & News

What is EuroGenetest?

EuroGenetest is an EU-funded Network of Excellence (NoE) with 5 Units looking at all aspects of genetic testing - Quality Management, Information Databases, Public Health, New

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[More](#)

What is a Genetic Test?

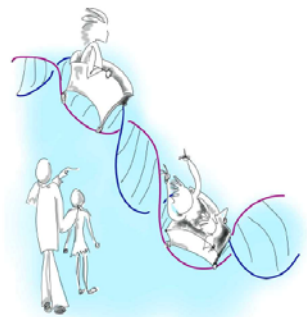


Medical Professionals

- [Genetic Counselling](#)
- [Ethical & Legal aspects](#)
- [Documents & guidelines](#)
- [Databases and Resources](#)
- [Patient Leaflets](#)



Predictive Testing



What Happens in a Genetics Laboratory?





Increase Public Awareness



Genetic Alliance UK
Supporting. Campaigning. Uniting.

Welcome to Genetic Alliance UK

Genetic Alliance UK is a national charity of over **130 patient organisations**, supporting all those affected by genetic conditions.

ANNOUNCEMENT:

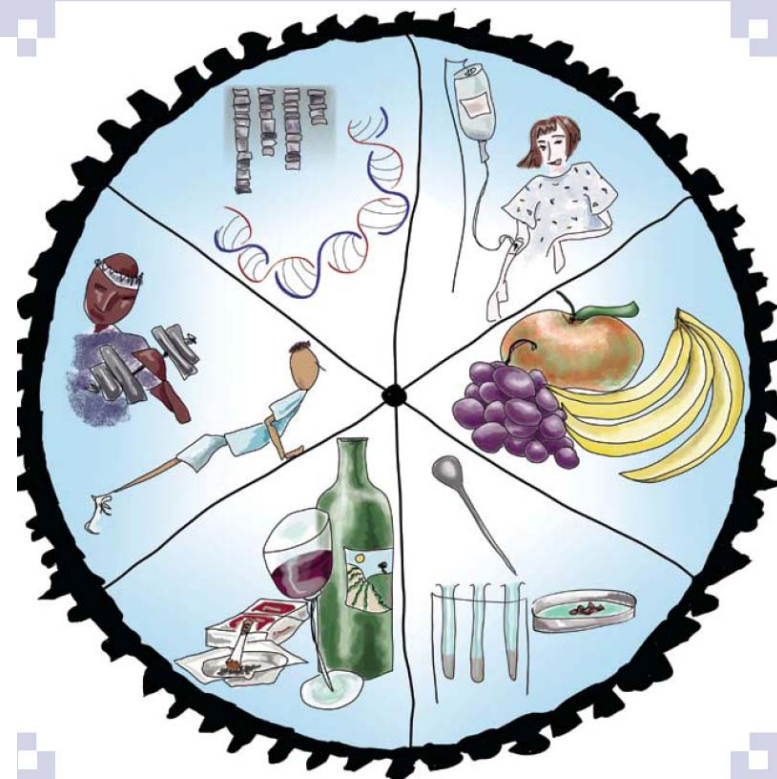
The Genetic Interest Group (GIG) is changing its visual identity. On 1st June 2010 the Genetic Interest Group will become Genetic Alliance UK. [Read more...](#)

Our Mission ▶

Genetic Alliance UK seeks to improve the lives of people affected by genetic conditions by ensuring that high quality services and information are available to all who need them.

Latest News ▶

24.06.10
Communications and Campaigns Intern
We are looking for an enthusiastic intern interested in gaining experience in communications, public affairs and campaigning and in



Over-the-counter Genetic Susceptibility Tests

Information for individuals, families and non-specialist health professionals



Food for thought

- DTD advertising, Co-opting of MD
- Provision over internet
- No academic consensus over utility, validity
- Private sector desire for profit is strong
- Technological imperative
- Desire to maximize results of human genome project
- Is autonomy absolute?
- Heterogeneity of companies, tests, information: hard to make “one-size-fits-all” statement, principle, law...
 - Are we ok with DTC whole genome sequencing??



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Merci---Thank you---Dank u

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Fonds Wetenschappelijk Onderzoek
Research Foundation - Flanders