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## National and International Regulations

Conference on Genetic Self Testing

Århus, January 14-15, 2009

2/16/09

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### Structure

- Trends and challenges
- Legal framework (Nat – Eur – Int)
- Nordic laws
- European Union
- International regulation (Council of Europe!)
- Opinions and statements
- Solutions (analogy from regulation on medicines)
- Existing possibilities

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## Trends and challenges

- Increasing interest, lots of reports, opinions, articles
- Many demand a general ban
- Genetic tests – other tests (metabolics, infections)
- Home sampling – Home testing
- Birth of a new profession – a phlebotomist (NeJM 2006;355:543-545) "a sample-taker"
- Nature of genetic tests?
  - Condition to be tested? medical - non-medical
  - Diagnostic-presymptomatic-predictive
  - Clinical utility (cure exists – no cure)
- Cross-border internet markets within EU / outside EU
- Is there anything we can do in the global internet markets?

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## Legal framework

- National Law
- European Law (EU)
- International Law (Council of Europe)
  - Increasing convergence between EU and CoE, e.g., human rights in EU as in CoE Human Rights Convention (Art 6 EC)
- Soft law (opinions, recommendations, guidelines)
- Court cases

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## Nordic legislation on genetic tests

- Only Sweden and Norway have laws that concern some issues of genetic tests, but not directly self-tests.
- Consumer legislation applicable.

Info on a biolaw network

- *Nordic Network for Research in Biomedical Law:*  
Academic network established in 2006, NordForsk funded 2008-2010. Administration in Uppsala (Prof. Elisabeth Rynning). [www.nordicnetwork.org](http://www.nordicnetwork.org)

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## Norway

- Bioteknologilov (2003-100)
  - § 1-1: --formålet at sikre av bioteknologi utnyttes til beste for mennesker--
  - § 5-2: Genetiske undersøkelser skal bare anvendes til medisinske formål med diagnostiske eller behandlingmessige siktemål.
  - § 5-3: Godkjenning av genetiske undersøkelser

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## European union legislation

- IVD directive 98/79/EC (See a study and policy proposal of Stuart Hogarth and David Mezler, Cambridge 2007 at [www.eshg.org](http://www.eshg.org)) -CE-mark.

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## European union activities

- European Group on Ethics in Science and New Technologies (EGE) Statement 2003 on advertising genetic tests via the Internet. Aim: alert civil society and decision-makers.
- Temporary committee's (Francesco Fiori) draft resolution on ELSI Human Genetics July 24, 2001 :
  - genetic diagnosis is a medical action, good clinical practice.
  - strict requirements to secure benefits of genetic analyses
  - coherent legal framework needed
  - only MDs and medical researchers with appropriate qualifications
  - resolution was rejected

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## Some examples from Europe

- FRANCE
  - Loi 2004-800 Loi de la bioéthique
  - Art. 16-10. –L'examen des caractéristiques génétiques d'une personne ne peut être entrepris qu'à des fins médicales ou de recherche scientifique.
- SWITZERLAND
  - Loi fédérale sur l'analyse génétique humaine (LAGH) du 8 oct 2004 (1.4.2007) Art.13 Droit de prescrire une analyse génétique-
  - 1) –que par un médecin habilité à exercer à titre indépendant ou sous la surveillance d'un tel médecin.
  - 2) – analyse génétique présymptomatique, prénatal ou family planning **médecin postgrade adéquate...**

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## Ethical councils and committees in Europe

- PORTUGAL
    - National council of Ethics for Life Sciences (CNECV),
    - Opinion on direct marketing of genetic tests to the public 56/CNECV/08 (July 2008)
  - THE UNITED KINGDOM
    - Human Genetics Commission: More genes direct 2007 & Genes direct 2003
  - FRANCE
    - CCNE Opinion no 86: Problems connected to marketing self-test kits for HIV screening and diagnosis of genetic disease (2004)
- > As governments' advisory bodies they have significance

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## International regulation

- Conventions, treaties, declarations etc..
- Binding international law v. soft law
- Council of Europe (CoE) most important in Europe (47 MS) ([www.coe.org/bioethics](http://www.coe.org/bioethics))
- Globally UNESCO ([www.unesco.org/bioethics](http://www.unesco.org/bioethics))
- CoE Biomedicine Convention 1997 ETS 164 and its additional protocols. Ratifications lacking in many western European countries (Nordic: IC, DK, NO ratified, FI pending (19.12.2008), SE ?)
- Even without ratifications has become "The Code" like WMA Helsinki declaration.

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## Biomed Convention

- Art 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 scientific research linked to health purposes, and subject to appropriate genetic counselling.

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## Gene test protocol 2008

- CETS 203
- Open to signatures 28/11/2008
- On Jan 12, 2009, three signatures (Finland, Luxembourg, Moldova)

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## CoE Genetic testing protocol

- Art 2. Scope: Applies to tests for health purposes.
- Art 5. Quality of genetic services:
  - comply with criteria for scientific and clinical validity,
  - quality assurance program and regular monitoring of labs
  - appropriately qualified professionals
- Art 6. Clinical utility as an essential criterium.
- Art 7. Individualised supervision.
- Art 8. Information and genetic counselling

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## Challenges for regulation

- How to treat different kinds of tests? E.g., predictive tests; susceptibility testing for multifactorial diseases, tests for non-medical conditions;? All under same provisions?
- How to safeguard analytical and clinical validity?
- Is clinical utility necessary? Or is "nice to know" enough?
- Is it legitimate for biomedical & bioethical rules to govern tests or hinder access to sports gene tests etc. (cf. fortunetellers, astrology, etc.)?
- Legislation should be clear and precise, but accumulation of scientific knowledge requires flexibility.
  - > Framework legislation and a authoritative agency for further directives.
  - > Biomed Conv. Art. 4 – Professional standards

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## Tentative solution in EU

- Pre-market review
- MD's referral for medical purposes required
- Revisit risk classification in IVD Directive
- Analogy from protection for medicines?
  - Medicinal products directive 65/65/EC
  - Free internal markets Art 28 principle, Art 30 exceptions limited, narrow interpretation (e.g., health protection).
  - E.g., prior authorisation procedure for personal imports: ECJ rulings C-312/01 (*Deutscher Apothekerverband v. DocMorris*), C-212/03 (Commission v. France)

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## Already possible

- Interfere in case of incorrect or misleading consumer marketing within EU.
- Nation countries can restrict import from outside EU!
- Example:

Finnish case KKO 2007:49. Many medicines are subject to MD's prescription. Custom control. Criminal offence under Penal Code 44 to import such medicines from abroad (India) either by self or via postorder at Internet. Illegal import was committed when the goods arrived at customs even though the customer never received it.



## Finsk strafflag, läkemedelsbrott

- **Strafflag 44:5 § (24.5.2002/400)**

### Läkemedelsbrott

Den som uppsåtligt eller av grov oaktsamhet i strid med läkemedelslagen eller en förordning om tillsyn över läkemedel som utfärdats med stöd av artiklarna 100 a eller 235 i Fördraget om upprättandet av Europeiska gemenskapen, eller i strid med bestämmelser eller allmänna eller särskilda föreskrifter som utfärdats med stöd av dem,

1) tillverkar, för in i landet, lagrar, håller till salu eller överlåter läkemedel som avses i läkemedelslagen,

2) i fråga om läkemedel som avses i läkemedelslagen, underlåter att göra anmälän, försummar sin informationsplikt eller underlåter att föra förteckning, eller

3) bryter mot ett förbud som en finsk tillsynsmyndighet eller Europeiska gemenskapernas kommission eller Europeiska unionens råd har utfärdat om läkemedel som avses i läkemedelslagen,

skall, om inte strängare straff för gärningen bestäms någon annanstans i lag, för *läkemedelsbrott* dömas till böter eller fängelse i högst ett år.

