WORKSHOP

In Vitro Diagnostic Medical Devices

Brussels, 26 February 2013

MEETING DOCUMENT
RELATED TO THE SECOND PART OF THE WORKSHOP ON "Regulation on Medical Devices (MDs) and In Vitro Diagnostic Medical Devices (IVDMDs)"
## CONTENTS

**Agenda** 3  
**Short Biographies of the Experts** 5  
**Presentations:**  
- Presentation by Ms Sabine Lecrenier 9  
- Presentation by Ms Sine Jensen 15  
- Presentation by Dr Laurence Lwoff 21  
- Presentation by Prof Hans-Georg Kamann 25  
- Presentation by Dr Katrin Grüber 31  
- Presentation by Prof David Barton 37
Workshop on
Regulation on In Vitro Diagnostic Medical Devices (IVDMDs)

Tuesday, 26 February 2013 from 16.10 to 18.00
European Parliament, Room ASP 1G2 Brussels

Policy Department A: Economy & Science
Committee on the Environment, Public Health and Food Safety (ENVI)

Part 2. The specific needs related to In vitro diagnostic medical devices

16.10 - 16.15 Opening by the Chair MEP Peter Liese

1. - The COM proposal on IVDMDs

16.15 - 16.25 Specifics of the IVDMDs proposal
Ms. Sabine Lecrenier, Head of Unit "Health Technology & Cosmetics", DG SANCO, European Commission

16.25 - 16.35 IVDMD manufacturers' point of view
Mr. Serge Bernasconi, European Diagnostic Manufacturers Association (EDMA), CEO

16.35 - 16.45 Self-testing devices: consumers’ needs and expectations
Ms Sine Jensen, Danish Consumer Council,
Senior Health Adviser

16.45 - 17.00 Questions & Answers

2. - Special aspects of DNA testing

17.00 - 17.10 Informed consent: a bioethical issue
Dr. Laurence Lwoff, Committee on Bioethics (DH-BIO), Bioethics Department of the Council of Europe, Secretary
17.10 - 17.20  Legal aspects related to the DNA testing  
Prof. Dr. Hans-Georg Kamann, Centre of European Law, University of Passau

17.20 - 17.30  Perspective of patients and disabled people  
Dr. Katrin Grüber, Mensch, Ethik und Wissenschaft

17.30 - 17.40  DNA testing: Current and future regulatory challenges  
Prof. David Barton, The European Society of Human Genetics

17.40 - 17.55  Questions & Answers

17.55 - 18.00  Conclusions by the Chair
SHORT BIOGRAPHIES OF EXPERTS

Ms Sabine Lecrenier

Ms Lecrenier is the Head of Unit for « Health Technology and Cosmetics » in the European Commission Health and Consumers Directorate-General.

Joining the European Commission in 1985, Ms Lecrenier has worked in various services in the context of the Internal Market (Free Movement of Goods and Services, Intellectual Property Rights, Notification Directive 98/34) and International Trade (Agreement on Technical Barriers to Trade).

Ms Lecrenier studied law at the University of Liège and holds a post-graduate degree in European Law at the College d’Europe in Bruges, Belgium. She is Maître de Conférence at the University of Liège in the field of EU Institutions and Cooperation with Developing Countries.

Mr Serge Bernasconi

Serge Bernasconi is Chief Executive Officer of MedTech Europe (the Alliance of European medical technology industry associations), Eucomed (the European medical devices industry association) and EDMA (the European in vitro diagnostics industry association).

Mr Bernasconi has more than 30 years experience in the world of pharmaceuticals and medical devices, working in companies such as Johnson & Johnson, Schering Plough in US and Europe, and more recently Medtronic.

In his capacity as President & International Regional Vice President of Medtronic France, he was elected President of APIDIM (The French Association for the Promotion of Innovation in Medical Devices), and Vice President and Treasurer of SNITEM (French Medical Technology Industry Association).

Ms Sine Jensen

Place of work: The Danish Consumer Council, Fiolstræde 17, P.O. Box 2188 DK-1017 Copenhagen K, Denmark

Education:
2001 MA in Educational Studies (pedagogy) and history, Roskilde University
1996 Nurse, Ringsted Nursing School
1989 Language student (main subject: English), Skt. Jørgens Grammar School

Work:
2007- Senior Health Adviser, the Danish Consumer Council
2001-2007 Policy Adviser, Dane Age (Danish Association of Senior Citizens)
1997-2001 Nurse, Christianshavn Domiciliary Care and National Hospital of Denmark, orthopedic surgical ward
1996-1997 Senior night nurse, Bispebjerg Hospital, ear-nose-throat ward
Member of:
- S-273 Health Informatics (Danish Standards)
- ISO TC 215 Health Informatics/WG 4 Safety and Security
- The Council for Adverse Drug Reactions (Danish Medicines Agency)
- Steering Group of the Institute for Rational Pharmacotherapy (Ministry of Health and Prevention)
- Pharmaceutical Injury Complaints Board (Ministry of Health and Prevention)
- Patient Insurance Scheme (Ministry of Health and Prevention)
- Patients’ Complaints Board (Ministry of Health and Prevention)
- The Drug Pricing Board (Ministry of Health and Prevention)
- The Reference Group for the establishment of a new complains and disciplinary system in the health area (Ministry of Health and Prevention)
- The Council for Alternative Treatments (The Danish National Board of Health)
- Advisory Board for the Nordic Cochrane Centre
- Patient Safety Council (Danish Society for Patient Safety)
- Advisory Committee of the Danish Institute for Quality and Accreditation in Healthcare

Dr Laurence Lwoff
Dr Laurence LWOFF holds a MSc. in reproductive physiology from the University of Paris VI – Jussieu (France). She then obtained her degree in agronomy from the Institut National Agronomique Paris-Grignon (France) in 1986 and received her PhD in molecular biology in 1989.

She joined the Council of Europe in 1991, where she was entrusted with the responsibilities of the Secretariat of the Conventions concerning the use of animals in agriculture and science, in the Directorate of Legal Affairs. In 1999, her responsibilities were extended to biotechnology. She was the Secretary of the International Conference of the Council of Europe on Ethical Issues Arising from the Applications of Biotechnology (Oviedo, Spain, May 1999). In 2002, she joined the Bioethics Department where she has been responsible in particular for the activities on human genetics and on the protection of the human embryo and the foetus. She was the Secretary of the Group in charge of the elaboration of the Additional Protocol to the Convention on Human Rights and Biomedicine, concerning Genetic Testing for Health Purposes.

She is currently the Secretary of the Committee on Bioethics(DH-BIO), intergovernmental committee in charge of the activities on the protection of human rights in the biomedical field, at the Council of Europe.

Prof. Dr. Hans-Goerg Kamann
Prof. Dr. Hans-Georg Kamann is an honorary professor for European and International Economic Law at the University of Passau, Director of the Centre of European Law at the University of Passau and an attorney at law and partner in the regulatory and government affairs department of the international law firm WilmerHale in Frankfurt and Brussels. Prof. Kamann’s expertise comprises questions of European constitutional law and regulation, European and German competition, state aid and procurement law, as well as WTO and international trade law. Prof. Kamann studied law and economics at the Universities of Passau and Bonn (1988-1994). He received a doctor’s degree (Ph.D. in law) in European Union Constitutional Law (“summa cum laude”) at the University of Passau (1996). Before entering private practice, he served as a stagiaire with the European Department of the German Federal
Ministry of Commerce (1997) and with the European Commission’s Legal Service (1998). Prof. Dr. Kamann has lectured on European and international regulation topics at the University of Passau, the University of Saarbrücken, the Frankfurt School of Finance & Management, and the Management Center Innsbruck.

Dr. Katrin Grüber

Head of the Institute Mensch, Ethik und Wissenschaft

Education in Biology and Chemistry at the University of Tuebingen to qualify as a teacher (1976 to 1982)
- PhD in Biology at the Department for Developmental Physiology, University of Tuebingen (1983 to 1987); stay at the University of East Anglia, UK (1985 to 1986)
- From 1990 to 2000 Member of the State Parliament of North Rhine Westfalia; 1990 Head of the Committee Man and Technology; 1995-2000 Deputy speaker of the Parliament
- From 1995 to 2000 Adjunct Professor of Political Science at the Faculty of Philosophy, Heinrich-Heine-University, Duesseldorf
- In 2001 Adjunct Professor of Political Science at the Institute of Nursing Science, University of Witten-Herdecke
- Member of the Ethics Commission of the German Nurses Association (DBfK)
- Director of the Institut Mensch, Ethik und Wissenschaft, Berlin

Special interests and background

- Political science
- Technology assessment
- Research policy on the national and European level
- Dialogue between science and civil society
- The role of experts, lay people, disabled and chronically ill people and their relatives in decision making process

Prof. David Barton

David Barton is Chief Scientist at the National Centre for Medical Genetics in Dublin, Ireland, and Adjunct Associate Professor in Molecular Genetics at University College Dublin. Having trained in Trinity College Dublin and The Queen’s University of Belfast, he carried out medical genetics research at Yale University and Cambridge University, where he first became involved in diagnostic genetics. He set up the NHS molecular genetics diagnostic laboratory in Cambridge in 1988 and then his current laboratory at the National Centre for Medical Genetics in Dublin in 1995. David Barton has been involved in work to monitor and improve the quality of genetic testing for many years, working with UK NEQAS, The European Molecular Genetics Quality Network (EMQN) and EuroGentest. He was co-ordinator of the EU CRMGEN project, developing certified reference materials for genetic testing and is now Chairman of EMQN and a member of the Genetic Services Quality Committee at the European Society of Human Genetics. David has published over 100 papers in peer-reviewed journals on many aspects of the molecular genetics of inherited disorders. David is involved in work to study and explain the regulation of genetic testing in the EuroGentest networks, in close collaboration with Dr Stuart Hogarth of King’s College London.
PRESENTATIONS

Presentation by Ms Sabine Lecrenier

Specifics of the proposal on in vitro diagnostic medical devices

S. LECRENIER
European Commission
Health and Consumers Directorate-General
Health Technology and Cosmetics Unit

European Parliament
26/2/2013

Current regulatory framework

Dir. 98/79/EC on in vitro diagnostic medical devices

Main objectives
- High level of patients and users safety
- Free movement of devices within the Internal Market

Main strengths
- Flexibility
- Cost-effectiveness
- SMEs friendly
- Support to innovation & competitiveness
**Why a revision?**

- To adapt to **technological and scientific progress**
- To address the **weaknesses of the system**
- To ensure a **uniform application of the rules**
- To provide **transparency**
- To take over **international developments**
- To respond to **public expectations**

---

**Scope**

- **Genetic tests**
- **Companion diagnostics**
- "**In house**" tests
- **Devices for diagnostic services at a distance**
General safety and performance requirements

- Adapted to technological and scientific progress
- Aligned with international guidance
- Instructions for use and labelling requirements reinforced, in particular for self-tests & near-patient tests

Risk classification

Positive list

4 risk classes

- **Class A**: Low Individual Risk and Low Public Health Risk
  *Example*: specimen receptacles

- **Class B**: Moderate Individual Risk and/or Low Public Health Risk
  *Example*: vitamin B12 tests

- **Class C**: High Individual Risk and/or Moderate Public Health Risk
  *Example*: genetic tests

- **Class D**: High Individual Risk and High Public Health Risk
  *Example*: HIV tests
Conformity assessment procedures

➢ Class A: Notified Body not involved except if:
  ▪ Sterile
  ▪ Measuring function
  ▪ Near-patient tests

➢ Class B: Notified Body involvement

➢ Class C: Notified Body involvement (+ pharmaceutical authority in case of companion diagnostics)

➢ Class D: Notified Body + EU Ref. Laboratory involvement (+ pharmaceutical authority in case of companion diagnostics)

Clinical evidence

➢ Clinical data to be submitted for pre-market assessment
  ✓ Scientific validity
  ✓ Analytical performance
  ✓ Clinical performance

➢ Rules on clinical performance studies and assessment coordination

➢ Post-market follow-up
THANK YOU FOR YOUR ATTENTION!

S. LECRENIER
European Commission
Health and Consumers Directorate-General
Health Technology and Cosmetics Unit

Presentation by Ms Sine Jensen

Self-testing – consumers’ needs and expectations

Sine Jensen
Danish Consumer Council

The right to a correct diagnosis

• PSA test – Cochrane Review: increases cancer by 70%

• Reality is not simple - great biological variation - when is it a “real disease” and when is it a “insignificant or sleeping disease”?

• We need to be able to trust the tests and requirements to the test are very important

• We don’t want consumers to become patients
Patient safety must come first

- We need solid clinical evidence of benefits and harms before we meet ‘market products’

- Only solid clinical evidence on benefits and harms can lead to innovation

- CE marking is not providing benefits nor is it preventing harms

- Patient harms will cost more

---

Essential evidence

- We need evidence for IVDs of class B, C, D

- Diagnostic test accuracy studies showing high sensitivity and specificity

- Randomised clinical trials showing more benefits than harms

- Systematic reviews with meta-analysis of two or more randomised clinical trials
More transparency during the process

• Transparency – of the competent authorities’ investigations

• Transparency – registration of all study protocols and trial protocols before inclusion of the first participants in a public registry

• Transparency – registration of all depersonalised individual participant data one year after study or trial closure in a public repository

Changing of the Notified Bodies is needed

• Regulation’s proposals regarding control system with the Notified Bodies are insufficient

• Either a new regulatory body on IVD medical devices

• Or a much stricter control of the Notified Bodies
Experience of self-testing in Denmark

• Project lead by the Board of Technology
  - could not recommend consumers to use self testing, the test are too uncertain

• Project lead by Danish Council of Ethics on genetic testing
  - Consumers should not use DNA testing, quality is too poor and nobody to help analysing the results

• Both projects call for MUCH better tests and much better consumer information

Potentials of self-testing

• Early diagnostic – better treatment, more choices (e.g. legal abortion)
• Better control of chronic diseases (e.g. diabetes)
• Autonomy and less focus on sickness (e.g. diabetes)
• Better compliance
• Discretion (e.g. sexual diseases)
• Less doctors consultation (e.g. when pregnancy test is negative)
• Security (fast result)
• Perhaps savings for the society...
Risk and disadvantages

- Unclear what is sickness and what is health
- False positive – over diagnosis and over treatment
- False negative – false security, late treatment
- Wrong use or bad technical functions
- Dependency
- The right not to know
- Health inequality can become worse – strong/less strong consumers
- Less contact to health-care professionals
- Demands from work or insurance companies to use test?

Conclusions

- Very good intentions in the proposal.

- Testing and approval of testing devices need to be strengthened – especially premarket assessment and the certifications process – must be based on solid clinical evidence

- Always more benefits than harm

- Call for more transparency at all levels
Thank you for your attention

FORBRUGERRÅDET

TÆNK
Presentation by Ms Laurence Lwoff

Informed Consent: A bioethical issue

Laurence Lwoff  
Bioethics Department  
Council of Europe  
http://www.coe.int/bioethics

Informed consent

Informed consent:  
- safeguard to ensure a person’s autonomy  
- process enabling a person to make a free and informed choice

- **Convention on Human Rights and Biomedicine (CETS No164, 1997)**  
  - No intervention in the health field on a person without his/her free and informed consent (Art. 5)  
  - Appropriate prior information on purpose, nature, consequences and risks of intervention  
  - Predictive test: Genetic counseling

- **Charter of Fundamental Rights**  
  - Art. 3.2  
  - Reference to the Convention on Human Rights and Biomedicine
Directive 98/79/EC on in vitro diagnostic medical devices

- Preamble: [33] Whereas, in view of the need to protect the integrity of the human person during sampling, collection and use of substances derived from the human body, it is appropriate to apply the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine; whereas, furthermore, national regulations relating to ethics continue to apply;

- Art. 1.4: “For the purposes of this Directive, the removal, collection and use of tissues, cells and substances of human origin shall be governed, in relation to ethics, by the principles laid down in the Convention of the Council of Europe for the protection of human rights and dignity of the human being with regard to the application of biology and medicine and by any Member States regulations on this matter.”

Genetic tests: HR concerns

- Convention on Human Rights and Biomedicine (predictive genetic test)
- Additional Protocol regarding Genetic Testing for Health Purposes

- Genetic test results:
  - Sensitive personal data: person and his/her family
  - Predictive: information on future health
    - Difficulty to understand the implications of the test
    - Capacity of analysis greater than capacity to act (« prevention » or treatment)
    - Difficulty of interpretation of test results
  - Risk for private life (person concerned and his/her family)
  - Persons not able to consent
**Requirements**
(Convention on Human Rights and Biomedicine and Its Additional Protocol)

- Appropriate information in particular on the purpose, the nature of the test and implications of its results for the individual concerned
- Free and informed consent
- Predictive genetic testing: appropriate support to ensure understanding: **genetic counselling**
  Form and extent: according to the implications of the test’s results for the person / his or her family, for procreation choices

⇒ Concern: Direct to Consumer genetic testing

---

**Further use**

**Information and consent:**

- Storage of samples and data
- Processing and possible further use of materials and data
Information leaflet for the general public
(Support of ESHG and EuroGentest)

Aims at:
- providing general objective information on genetic tests, including their nature and the potential implications of their results;
- presenting the different type of test available, their applications in the medical field and the extent and limit of the significance of the information resulting from these tests;
- suggesting questions to ask, when considering a genetic test.

laurence.lwoff@coe.int

www.coe.int/bioethics
Presentation by Mr Hans-Georg Kamann

Legal Aspects related to Genetic Testing

Workshop of the Committee on Environment, Public Health and Food Safety of the European Parliament on the "Regulation on medical devices (MDs) and in vitro diagnostic medical devices (IVDMDs)"

Prof. Dr. Hans-Georg Kamann
Centre of European Law at the University of Passau
26 February 2013

The Starting Point

August 2001: CEP Opinion for EPP-Group
- European Community is authorized on the basis of the internal market competences to adopt legislation in the area of human genetics and reproductive medicine, in particular on the admissibility and conditions of DNA-analysis, as well as prenatal genome analysis
- Community legislator would have to take into consideration in particular the European fundamental rights laid down in the Charter of Fundamental Rights (Charter)

- Call for EU provisions/standards for genetic testing
- Three main political requests:
  - "...that genetic testing and analysis must be conducted under clear rules within the frame of competent, independent and personal counselling which must cover medical, ethical, social, psychological and legal aspects;
  - "...that genetic testing analysis and diagnosis data must remain confidential and should be used only for the benefit of the person requiring such tests, with the exception of tests undertaken for clearly defined scientific or criminal investigation purposes, therefore such tests should be inadmissible for social or recruitment purposes, and should not jeopardise personal privacy and dignity;
  - "... that determination of sex in connection with prenatal diagnosis should be permitted only – if at all – if there is a risk of serious gender specific hereditary diseases."
The Legal Issues

26 September 2012: Commission Proposal for a Regulation on in vitro diagnostic medical devices (IVD-Regulation)

- No provisions taking account of the Parliaments’ Resolution of 21 November 2002.

13 September 2012: Request by Dr. Peter Liese, MEP, to CEP to “update” the CEP Opinion 2001.

- Three main questions:
  - Have there been any new developments that could influence the findings of the CEP Opinion 2001?
  - Is the European Union competent to adopt legislation implementing the requests made by the Parliament in its Resolution of 21 November 2002?
  - It is legally possible to implement the requests made by the Parliament in the framework of the proposed IVD-Regulation?

Developments 1

- Relevant Union competences have been endorsed under the Lisbon Treaty
  - New Article 168 (4) (c) TFEU: “high standards of quality and safety for... devices for medical use”
  - ECJ: further strengthening of the internal market competences under Article 95 EC Treaty (now Article 114 TFEU)

- New level of Protection of Fundamental Rights under the Lisbon Treaty
  - Charter is binding primary law (Article 6 (1) TEU)
  - In the fields of medicine and biology, in particular the free and informed consent of the person concerned must be respected (Article 3 (2) (a) of the Charter)
  - New value of the European Convention for the Protection of Human Rights and Fundamental Freedoms (ECHR) (Article 6 (2), (3) TEU, Article 53 of the Charter)
Developments II

- ECJ, Brüstle vs. Greenpeace, C-34/10:
  - fundamental rights to human dignity and integrity (Articles 1 and 3 (1) of the Charter) relevant for prenatal life
    “although it seeks to promote investment in the field of biotechnology, use of biological material originating from humans must be consistent with regard for fundamental rights and, in particular, the dignity of the person [...]”
    “[…] that the European Union legislator intended to exclude any possibility of patentability where respect for human dignity could thereby be affected. It follows that the concept of ‘human embryo’ [...] must be understood in a wide sense.”

- European Court of Human Rights (S.H. vs Austria, Pavan vs Italy):
  - Couple’s right to have a child by use of medically assisted procreation (supported by pre-implantation diagnosis) is within the scope of the fundamental right to private and family life (Article 8 ECHR)

Developments III

- New International Treaties and Standards
  - Additional Protocol on Genetic Tests to the Bioethics Convention (signed by Finland, France, Luxembourg and Slovenia)
    - Prohibition of discrimination on grounds of genetic heritage (Article 4)
    - Obligatory information before genetic test (Article 8 (1))
    - Availability of genetic counselling before predictive genetic tests (Article 8 (2))
    - Free and informed consent (Article 9)
  - UN Convention on the Rights of Persons with Disabilities (ratified by EU)
    - Protection against discrimination on basis of disability (Article 5)
    - Persons with disabilities shall enjoy inherent right to life on an equal basis (Article 10)
  - OECD Guidelines for Quality Assurance for Molecular Genetic Testing
    - Principle of quality assurance
    - Principle of informed consent
    - Principle of genetic counselling
    - Protection of genetic information
Legal Consequences I

- The EU may adopt provisions addressing the Parliaments’ political requests as to genetic testing in the framework of the IVD-Regulation
  - Genetic testing (and prenatal diagnosis in particular) as an area posing sensible ethical issues falls within the scope of application of Union law
  - Under Articles 114 and 168 (4) (c) TFEU, the EU has the competence to adopt provisions on the use of in vitro diagnostics for the purpose of genetic (and in particular prenatal) testing
    - Likewise Regulation 1107/2009 regulates the use of PPPs

Legal Consequences II

- When considering to add provisions to the IVD-Regulation, the EU legislator is required to respect the relevant fundamental rights of the Charter and the ECHR, and the new international treaties and standards.
  - E.g. right to respect of human dignity (Article 1) and protection of life (Article 2), physical integrity and informed consent (Article 3 (1), (2) of the Charter)
  - Additional Protocol on Genetic Testing sets the possible standard
- In accordance with Article 168 (4) (c) TFEU, the EU legislator may allow Member States to maintain (or introduce) more stringent national legislation for reasons of health protection
  - Likewise Regulation 1107/2009 allows for national derogations on authorisation or labelling requirements for PPPs
- For concrete proposals, see CEP Opinion
Many thanks for your attention!

Prof. Dr. Hans-Georg Kamann
Centre of European Law at the University of

contact:
WilmerHale, Ulmenstr. 37-39, 60325 Frankfurt
Tel.: 069 27 10 78 004
Fax: 069 27 10 78 100
Email: hans-georg.kamann@wilmerhale.com
Presentation by Dr Katrin Grüber

European Parliament
Regulation on Medical Devices (MDs)
and In Vitro Diagnostic Medical Devices (IVDMDs)

The Perspective of Patients and Persons with Disabilities

Dr. Katrin Grüber
Institut Mensch, Ethik und Wissenschaft

26 February 2013

UN Convention on the Rights of Persons with Disabilities (UN-CRPD)

- Ratified by the European Union
  - 23rd December 2010
- Purpose (Article 1)
  - To promote, protect and ensure the full and equal enjoyment of all human rights and fundamental freedoms by all persons with disabilities
  - To promote respect for their inherent dignity
Promoting Respect for the Inherent Dignity of Persons with Disabilities

- 2(2) Concerning a congenital abnormality
- 2(2) Determining certain genetic characteristics of the embryo or foetus which, according to the generally accepted views of science and technology, might impair its health before or after birth

Principles of the UN-CRPD

- To mainstream disability in existing processes
- To raise awareness
- Participation of persons with disabilities is important to correctly identify specific needs
Regulation on In Vitro Diagnostic Medical Devices (IVDMDs)

- **Preamble**
  - *This Regulation respects the UN-CRPD, as ratified by the EU on 23.12.2010*

- **Medical Device Coordination Group (MDCG)**
  - **Members**
    - Expertise in the field of medical devices and IVDMDs and
    - *Representatives dedicated to the realisation of patient interests, consumer interests and disabled persons’ and self-help issues*

---

Duty to Inform
A Prerequisite for Informed Consent Before Testing

- **Legal regulation**
  - in Austria, Czech Republic, France, Germany, Portugal

- **Content**
  - Information given by the responsible medical person regarding the nature, meaning and scope of genetic examination

- **Requirement**
  - Information provided should be comprehensive, comprehensible and up to date

- **Precondition**
  - Information on clinical utility of the genetic test
Counselling Before and After Genetic Testing

- Content: Counselling on medical, psychological and social issues of genetic testing
- Referring to non-medical counselling (Austria)
- Referring to support possibilities (Germany)
- Offering genetic counselling consultations and psychological and social follow-up (Portugal)

- Responsible medical person needs to be qualified in risk communication and psychological and social issues

OECD-Guidelines

- Pre-test and post-test genetic counselling should be available
- Should be proportionate and appropriate to
  - The characteristics of the test
  - The test limitations
  - The potential for harm
  - The relevance of test results to individuals and their relatives*

*OECD guidelines
References

- Czech Republic: Act on specific health care services, 2012.
Regulation of Genetic Testing

David Barton
European Society of Human Genetics
EuroGentest
European Molecular Genetics Quality Network

"Regulation on Medical Devices and In Vitro Diagnostic Medical Devices"
European Parliament, 26 February, 2013

Why Genetic Testing?

• A paradigm for specialist testing
• Over 80% of rare diseases are genetic
• Rapid pace of innovation
• High potential for harm
• International activity (66% of laboratories)
• All patients deserve the same protection
• Regulation needs to be at EU level
Things we welcome

- Reformed risk classification
  - All human genetic testing is Class C
  - Pre-market assessment for all commercial genetic tests
- Retention of Health Institution Exemption
  - Essential for specialist and rare disease testing
- Restriction of the HI Exemption to accredited laboratories
  - Balances test availability with patient safety

Clarification needed

- Transparency & openness
  - Article 24 vs. Recital 32
  - Summary or all trial data? (no cherry-picking data!)
- Health Institution Definition
  - Clarification that commercial labs are not HIs
- DTC tests
  - are included (Art. 5.2) but language is not clear
  - Rider: “Without prejudice to national legislation regarding the exercise of the medical profession”
Issues Still To Be Addressed

• Role of EMA (vs Commission ??? Cttee)
  – Oversight of Notified Bodies
  – Review of Class D (and some other) devices
  – Pharmacogenetics: companion diagnostics
  – Simultaneous approval of drugs and diagnostics

• Laboratory-developed tests
  – Class D devices
  – Definition of a label

Issues Still To Be Addressed

• Clinical performance studies
  – Definition of scientific validity
  – Types of data which are acceptable
  – Types of data required in clinical performance study report

• Risk classification
  – novelty
  – What are “established and standardised” devices?
  – Selection of patients: include prognosis
Detailed Analysis

Across entire range of proposals
  – EuroGentest/ESHG position
  – COM Proposal
  – EuroGentest/ESHG response
• Available at www.eurogentest.org
• Copies available here today

Acknowledgement: Dr Stuart Hogarth
Policy Department A
Economic and Scientific Policy

Role
Policy departments are research units that provide specialised advice to committees, inter-parliamentary delegations and other parliamentary bodies.

Policy Areas
- Economic and Monetary Affairs
- Employment and Social Affairs
- Environment, Public Health and Food Safety
- Industry, Research and Energy
- Internal Market and Consumer Protection

Documents