

## EUREGIO II: WP 6

### the role that European Law can play

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# The Content

## The Contents

“The EUREGIO II project wants to deal more intensively with problems of EU health legislation with regard to the **exchange of data/information** (especially in eHealth) as well as **liability / tort rights** in the provision of cross-border health care services. Both topics have been chosen as they highlight the two dimensions: liability rights and data protection can be analysed from the patient and the professional perspective”

## The Rationale

- At the moment patients and professionals are suffering from legal uncertainty.
- The ambitious part is to set up regulations which are applicable to all MS in diverse regulatory fields.
- Traditional product regulations are a part of the aquis. Data protection has been partly harmonised in the mid 90's. Tort Law is still part of the National domain. Europe for Patients aims to change this. Cross border services are the Litmus test for these regulations.

# The Context

## **The future framework: Principles for Health in the EU Health Strategy**

- **Common “Health Values” for Europe = evidence-based, ethically and legally acceptable policies**
- **Health is Wealth = investments in health are not “costs”**
- **Health in all Policies = integrating health in all policies including policies outside the traditional health sector**
- **EU and Global Health = supporting global health and addressing global health needs, in particular in the area of infectious diseases**

## The future framework: EU Actions

- **Fostering Good Health in Ageing Europe: early and targeted prevention, focussing on the burden of disease, supporting health life styles in Europe**
- **Protecting Citizens from Health Threats: risk assessment, quality assurance, preparing for pandemic situations and new threats deriving from trade, travel and migration investments in health are not “costs”**
- **Supporting Dynamic Health Systems and New Technologies: Genomics is one cornerstone of the new field of European actions; new technologies and a paradigm shift to targeted interventions and prevention also require a PHELSI evaluation**

## The Legal Enterprise ?

## Health in all Policies in the EC Treaty

**Art 152 par 1: A high level of human health protection shall be ensured in the definition and implementation of all Community policies and activities.** Community action, which shall complement national policies, shall be directed towards **improving public health, preventing human illness and diseases**, and obviating sources of danger to human health. Such action shall cover the **fight against the major health scourges**, by promoting research into their causes, their transmission and their **prevention**, as well as **health information and education**.

## Health in all Policies in the EC Treaty (II)

Art 95 par 3: The Commission, in its proposals envisaged in paragraph 1 concerning **health**, safety, environmental protection and consumer protection, will take as a base a **high level of protection**, taking account in particular of **any new development based on scientific facts**. Within their respective powers, the European Parliament and the Council will also seek to achieve this objective.

## Health in all Policies in the Lisbon Treaty

**Art 152 par 2 NEW: It shall....encourage...", in particular initiatives aiming at the establishment of guidelines and indicators, the organisation of exchange of best practice, and the preparation of the necessary elements for periodic monitoring and evaluation. The European Parliament shall be kept fully informed.";**

## Health in all Policies (HiAP): A ...not so.... new doctrine

„The purpose of the doctrine is to highlight ways in which population health can be improved through coherent action in sectors other than health sector. In practice this means that health arguments are taken into account in decision making with relevance to the determinants of health.

The institutionalisation will serve as an opportunity to pool and exchange information, experiences and expertise on the principle of Health in All Policies. The best knowledge available at the current time will be distributed - together with examples of good practices, including impact assessments”.

## The challenge: Translating Knowledge into Policies

- The success of the Health in all Policies approach depends on the ability of institutions to translate emerging knowledge into policies
- So far there is no constant up- and downstream of knowledge between life sciences and policy making in emerging areas like genomics
- In order to have an impact, scientists have to deliver messages which can be translated into actions. It is useless to report an increased relative risk of 1.09, it may make a substantial difference to report a clearly defined attributable risk (AR) which can be tackled by a product or process regulation.

# The Future



Brussels, 2.7.2008  
COM(2008) 414 final

2008/0142 (COD)

Proposal for a

**DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL**

**on the application of patients' rights in cross-border healthcare**

(presented by the Commission)

{SEC(2008) 2163}

{SEC(2008) 2164}

{SEC(2008) 2183}

- provide sufficient clarity about rights to be reimbursed for healthcare provided in other Member States;
- and ensure that the necessary requirements for high-quality, safe and efficient healthcare are ensured for cross-border care.

Whenever healthcare is provided, it is vital for patients to ensure:

- clear information that enables people to make informed choices about their healthcare;
- mechanisms for ensuring the quality and safety of the healthcare that is provided;
- continuity of care between different treating professionals and organisations;
- and mechanisms to ensure appropriate remedies and compensation for harm arising from healthcare.

## The framework of the proposed Directive:

“Member States are responsible for the organisation and delivery of health services and medical care. They are in particular responsible for determining which rules will apply to the reimbursement of patients and to the provision of health care. This proposal changes nothing in this respect. It is important to underline that this initiative does not alter the Member States' choice of the rules which will be applicable to a specific case. Instead, this framework is designed to facilitate European cooperation on healthcare, such as for European networks of centres of reference; sharing assessments of new health technologies; or using information and communication technology to provide more efficient healthcare ("e-health").

## The Work Programme of WP 6

## The framework for Liability and Tort Law

- Product and Service Quality fall under the competence of the EC
- Health is increasingly “market” driven in many MS; patients become consumers who choose services and products abroad.
- Health lawyers are concerned about legally enforceable standards (cross border HTA) and the liability / information duties of professionals.
- EU has identified liability (and legally enforceable medical standards) as a key obstacle in the Europe for Patients initiative. The proposed Directive reflects this.

## The framework for Data Protection

- Patients are travelling and so do the data of patients. There are mechanisms for reimbursement data but there is no integration of health data systems beyond national borderlines.
- Cross-border services are hampered if professionals are unable to exchange data. Euregios demonstrate that professionals from different MS need to work together to create a maximum of service for patients.
- The Data Protection Directive (DPD) has changed the situation little as health is not fully harmonised:

### Core Legal provisions in the DPD:

- Art 8 par 3 DPD: Paragraph 1 shall not apply where processing of the data is required for the purposes of **preventive medicine**, medical diagnosis, the provision of care or treatment or the **management of health-care services**, and where those data are processed by a health professional subject under national law or rules established by national competent bodies to the obligation of **professional secrecy** or by another person also subject to an equivalent **obligation of secrecy**.
- Art 8 par 4 DPD: Subject to the provision of suitable safeguards, Member States **may**, for reasons of substantial **public interest**, lay down exemptions in addition to those laid down in paragraph 2 either by national law or by decision of the supervisory authority.
- Health regulations require a solid evidence base; Public Health and health policies are not mentioned in Art 8 par 3 DPD. They may fall under Art 8 par 4 DPD but this article is constructed as a “harmonised non-harmonisation”. Individual health services are covered by Art. 8 par 3, but there is still a major impact of the transposition of the Directive on the situation in Euregios.

## The Outcome

Legal report on the effect of tort and data protection rights on cross-border health care **(M 33)**