

Work in Progress

The citizen is the real minister of health

Michael Tremblay PhD

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The Community's authority to act

Article 153 of the Treaty establishing the European Community (TEC):

1. In order to promote the interests of consumers and to ensure a high level of consumer protection, the Community shall contribute to protecting the health, safety and economic interests of consumers, as well as to promoting their right to information, education and to organise themselves in order to safeguard their interests

E-health's home in the EU

Health and Consumer Protection Directorate-General or the Information Society Directorate-General. Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions on the health strategy of the European Community, (COM/2000/0285 final)

The Council of Europe's authority

European Social Charter, 1961

Article 11 – The right to protection of health

With a view to ensuring the effective exercise of the right to protection of health, the Contracting Parties undertake, either directly or in co-operation with public or private organisations, to take appropriate measures designed inter alia:

- *to remove as far as possible the causes of ill-health;*
- *to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;*
- *to prevent as far as possible epidemic, endemic and other diseases.*

The European Court of Justice position

The Court of Justice argued:

- that the Member States have the power to organise their social security systems (resp. 21-22; 17-18);
- that nonetheless, social security provisions are not exempt from the application of the basic principle of free movement (resp. 24-25; 20-21);
- that article 22 of Regulation n° 1408/71, which also requires prior authorisation for coverage of care provided in another Member State on behalf of the competent institution, but according to the tariffs in effect in the State where the care was

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provided, does not prevent reimbursement at the tariffs in effect in the State of affiliation in the absence of prior authorisation (resp. 27-29; 25-27);

- that the prior authorisation requirement discourages insured persons from seeking care from service providers or suppliers of medical goods established in other Member States and therefore constitutes a barrier to the free movement of patients (34-36; 34-35);
- that in this instance, the requirement for prior authorisation could not be justified, either on the basis of a serious threat to the financial balance of the social security system, or for reasons related to public health (protection of the quality of medical services, maintenance of a medical and hospital service that is balanced and accessible to everyone) (resp. 40-43; 40-42, 47, 52).

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The e-health agenda

- a country's health system now may be said to encompass domestic resources, and those other resources in other EU member states that citizens can have access to, including ambulatory care, in-patient services, as well virtually complete portability of benefits, goods and services
- Council of Europe is addressing e-health across a wide range of fronts, from health and media to patient use of the Internet.
- e-commerce phenomenon and the globalisation in general have put pressures on the legislators to harmonise also the regulations in health and social sectors.[In Decision 1400/97/EC of the European Parliament and of the Council adopting a program of Community action on health monitoring within the framework for action in the field of public health (1997 to 2001) one of the objectives was to enable the establishment of an effective and reliable system for the transfer and sharing of health data and indicators using telematic interchange of the data as the principal means]
- legal issues are not well understood [Tremblay, Telemedicine: Legal Issues, UK DH; Hodge, J.G. – Gostin, L.O. – Jacobson, P.D., Legal issues concerning electronic health: privacy, quality and liability, JAMA 282(15): 1466-71, Oct 20 1999 (Source: Abstract of the article in Telemedicine Information Exchange (TIE) Bibliographic Database, <http://tie2.telemed.org/Citations.asp?ID=7944>)]
- harmonisation may in practice arise even from the difficulty to maintain the restrictions in practice. One good example such ineffectiveness is the commercial communications of pharmaceuticals: unlike in European Union, the marketing of prescription medicine to the patients is allowed for example in the USA and New Zealand. Partly due to this imbalance of the markets, the European Commission has recently introduced proposals to review the EU pharmaceutical legislation, which includes the idea of opening up the marketing of prescription medicine directly to consumers. [Commission proposes comprehensive reform of EU Pharmaceutical Legislation, Press release Brussels 18 July, 2001 <http://pharmacos.eudra.org/F2/review/index.htm>. The three Proposals of the reforms are (1) the Proposal for a Regulation of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products;
- (2) the Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/83/EC on the Community code relating to medicinal products for human use
- and (3) the Proposal for a Directive of the European Parliament and of the Council amending Directive 2001/82/EC on the Community code relating to veterinary medicinal products]
- the liberalisation would initially focus on AIDS, diabetes and asthma drugs.

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- raises concerns among the health professionals on the impacts to the consumer behaviour and doubt that the thrust for the liberalization is rather economic-driven than concern over the patients' access to information.[example: page 7 of the Publication Vol 19, nr. 4, September 2001 of the Association for Physicians for Social Responsibility – Finland (PSRF) (LSV-tiedote, Lääkärin Sosiaalinen vastuu ry) <http://www.kaapeli.fi/~lsv/tied401.pdf>. See also the statement January 21, 2002 of the PSRF on the proposal for reform of the pharmaceutical legislation in <http://www.kaapeli.fi/~lsv/>]
- the licensing schemes are national based and thus, might constrain service provider from fully exploiting the possibilities of e-health
- the regulation concerning patient insurance systems may have to be revised irrespective of whether tax or insurance-based.
- already European harmonisation on the mutual recognition of the qualifications in medicine and coordination of provisions in respect of the activities of the doctors; does this adequately deal with malpractice?

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Current state of e-health affairs

- advancements have concentrated more on the technical innovations than constructing general infrastructure for effectively enforcing the application in practice.
- more comprehensive and system-oriented approach has to be adopted.
- not much legislation in European level concerning specifically the health care and social sectors, the reasons being the dissimilar requirements of national regulations, and due to the public nature services they appear fairly difficult to harmonise

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Consumer sovereignty

- the EU agenda is towards liberalisation, and the creation of a single European market in goods and services
- patient mobility is now a feature of the free movement agenda
- consumer protection at EU level will need to take account of increasing likelihood of cross-border health care, even though current state of movement is less than half of 1% of spending.
- European view of the citizen, as forged by the ECJ generally is of a rational consumer, able to make up their minds so long as they have have informed freedom of choice; restrictions here are incompatible with the principles of the European Union; and may be in conflict with Human Rights protections
- EU agenda has been to erode the pre-eminence of state monopolies and open up markets; these principles applied in such areas as telecoms, are now part of the policy and legal landscape and figure in any key decision-making on health.

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- In view of the diversity in health care systems within the EU, it is essential for (medical) consumer protection that patients should have all the necessary data required to make an informed decision about going to another Member State to receive medical goods and services. This data includes accurate information about the price, the extent of their social security coverage, the quality of care, the medical competence and practices they might expect. [aim]
- Technological and scientific developments in the field of health care are leading towards more concentration of medical know-how, financial resources and facilities in centres of excellence. These hospital centres are developing a European and even international strategy. With a view to facilitating access to these centres for the benefit of all EU citizens, the Commission could encourage Member States to prepare an operational framework guaranteeing fair financing, financial accessibility and quality of care. [aim]
- in the light of sometimes alarming waiting lists, the co-ordination mechanism appears to offer patients a remedy against rationing policies that would adversely affect their state of health and their basic right of access to care. Indeed authorisation for treatment abroad may not be refused if the treatment is covered by their health care scheme and cannot be provided within "*the time normally necessary*" (Article 22(2)(2)). [aim]
- The quality of health care and health safety need just as much attention at Community level as do food and environmental safety. Contrary to the ECJ cases, the quality of care is by no means guaranteed by the mutual recognition of diplomas, which primarily covers mobility for health professionals. The new Community strategy defined in the field of public health could provide a firm basis for initiating a common reflection on a non-binding frame of reference for quality standards, the criteria for good medical practices, the rules governing the equivalence of medical skills and services, hospital accreditation etc. [aim]

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The new policy world

- Challenges facing government increasingly are ones that government alone cannot solve, but requires partnership
 - Technology and technological change move faster than policy can respond, but consumers in a market are more likely to
 - Technology assessment methods benefit policy makers, but inhibit innovation and experimentation
 - Innovation in health requires pluralism, more compatible with a liberal view of human nature
- Most policy thinking in health is focused on ways to control the external world not on ways to harness change to learn
 - The policy process should be one fundamentally of learning – a dynamic partnership with events for policy made in the world