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INTRODUCTION

"The rights of EU citizens to establish themselves or to provide services anywhere in the EU are fundamental principles of European Community law. Regulations which only recognise professional qualifications of a particular jurisdiction present obstacles to these fundamental freedoms."

The Consultation is the culmination of a methodical review of health since Lisbon: Long term care for the Elderly, the High Level Reflection Process, the Reflection Process, High level Group on Health Services and Medical Care.

The Consultation is wisely broad in its remit:

"Cross-border care has consequences for all health services, whether provided across borders or not"

The ECU welcomes the opportunity to submit to the Consultation process. The ECU founded in 1932, represent 18 national chiropractic associations, 3500 individual members who provide care for millions of patients across Europe.

Services account for 70% of economic activity in Europe, of which one seventh, and rising, is health care. Health care is not synonymous with "medical care". Millions of patients across the continent avail themselves of health care which is non-conventional, alternative, non-orthodox. Several of these professions prove to be evidence-based, of high quality, safe, efficacious, effective, and cost-effective. These are the emerging, innovative, knowledge-based professions that will have an ever important roll to play in helping to improve the health of Europe's citizens – if legacy, monopolistic incumbents allow.

(House of Lords, Science and Technology - Sixth Report, session 1999-2000
http://www.publications.parliament.uk/pa/ld199900/ldselect/ldsctech/123/12301.htm

Raschetti, Menniti, Ippolito, Foroela, Bologna, Sebastiani, Sabbadini. Le terapie nonconvenzionali in Italia: I primi dati. Notiziario ISS – Vol 14 n.7/8, Luglio/Agosto 2001;
http://www.iss.it/ricerca/index.htm)

The Lisbon objectives aim to create a knowledge based economy. Europe seeks to close a gap with respect to the USA , in terms of innovation accumulated in the 90's.(Il Rapporto CEIS – Sanità 2006; Centre for Economic and International Studies – Sanità, Facoltà di Economia, Università degli Studi di Roma "Tor Vergata)

The Research and Development FP7 project has been designed to provide ample opportunity to smaller players such as emerging and innovative health care professions. The Community Action Programme, is inclusive in its terms of reference. A new European Health Strategy should continue this progressive approach; embrace new and alternative professions and promote the objectives of universal access to high-quality healthcare founded on the principles of equity, equality and solidarity. Emerging health care professions can contribute to improving efficiency, prevention and health promotion.

Since the Lannoy Report, non-conventional medicine has been largely unconsidered at a European level. Standards of care, legislation and regulation vary widely between States.
(Legal Status of Traditional Medicine and Complementary/Alternative Medicine: A Worldwide Review
http://whqlibdoc.who.int/hq/2001/WHO_EDM_TRM_2001.2.pdf)

One statement from the Consultation Communication needs particular attention and will be considered in the replies to questions 6, 7 and 9
"European competition policy also helps to ensure a level playing field for economic actors providing and financing health care "

The playing field in the health care market is not level. This has been illustrated recently by an OECD Roundtable which included State and EC Antitrust officials (OECD personal communication). The report details the benefits of competition in health care. . Competition in health care has not been methodically examined by the EU institutions. Meanwhile in some countries alternative medicine practitioners are actually regulated and conventional and included in European practice guidelines (www.backpaineurope.org) while in other countries practitioners may suffer oppression, fines, persecution and closure for offering safe, effective evidence-based care. Chiropractic is an example of a profession that is perfectly integrated into conventional health schemes in some countries while being non-conventional, verging on illegal in others.

Choice and sustainability are compatible. Allowing new professions to emerge and thrive affords patients greater choice. More efficacious, effective and cost-effective procedures will emerge; creating new efficiencies and jobs and savings in this vibrant sector of the economy. The House of Lords in 2000 and the Prince of Wales Foundation have respectively elaborated useful classifications of alternative health care providers and their potential benefits to health and the economy.

ECU agrees with the goal of ensuring clarity and certainty in matters of health and mobility

Question 1: what is the current impact (local, regional, national) of cross-border healthcare on accessibility, quality and financial sustainability of healthcare systems, and how might this evolve?

ACCESSIBILITY

Emerging or Innovative health care Professions in the field of Traditional Medicine or Complementary and Alternative Medicine are widely utilised by Europeans. Inequality of access persists throughout Europe. Currently it is rare to unheard of for a patient to obtain reimbursement for non-conventional care in a cross-border situation. Obstacles to the free movement of professionals exist since complementary and alternative professions are not adequately catered for in the sectorial and general directives systems.

QUALITY

Paradoxically quality is often compromised through excessive regulation. Some countries allow only regulated health care professionals (generally orthodox medicine) to practice non-conventional health care professions.

(European Union and Alternative Medicine: Some institutional and legal impacts on a developing field; Orsolya Varga1 and Péter Kakuk; Integrative Medicine Insights 2006: 2 27–33 http://www.la-press.com/IMI-1-Orsolya(Sc).pdf)

The result is orthodox medicine operators are able to practice professions for which they have relatively inadequate training while qualified operators are excluded from working and practicing their speciality.

(WHO guidelines on basic training and safety in chiropractic, http://www.who.int/medicines/areas/traditional/Chiro-Guidelines.pdf)

A recent example is the Region of Lombardia which allows reimbursement for an arbitrary three spinal column treatments if performed by a medical doctor to the exclusion of properly qualified chiropractors. Recent WHO Guidelines state that the chiropractor is the operator with the most appropriate training. Medical doctors are not always the most appropriate professional figure in musculoskeletal disorders:

Improved Education in Musculoskeletal Conditions is necessary for doctors,
Acheson, Dreinhofer, Woolf
http://www.who.int/bulletin/volumes/81/9/en/
Bulletin of the World Health Organisation
Volume 81, No. 9, 2003, 629-697

Educational Deficiencies in Musculoskeletal Medicine
Freedman, Bernstein (2002)
J Bone and Joint Surg 84A (4):604-608

Knowledge of Musculoskeletal Medicine at Undergraduate and Postgraduate Levels
Vlahos, Broadhurst et al (2002)
Australasian Musculoskeletal Medicine, May 2002:28-32

FINANCIAL SUSTAINABILITY

Currently this is not threatened by cross-border healthcare. Eurostat does not keep statistics on the patients that move country to seek non-conventional health care. Figures for the movement of these professionals are also inaccurate. The European Chiropractors' Union has 3500 members. These are not reflected on the EC websites:

http://ec.europa.eu/internal_market/qualifications/regprof/stats/dsp_stats.cfm?profId=1320

One of the aims of the European Union is to promote the free movement of people. Regulations in health care stifle this movement in the emerging health care professions, reducing innovation with subsequent consequences for the economy and health in general.

EVOLUTION OF HEALTH CARE SYSTEMS – Light Regulation

The Smallwood Report illustrates the financial benefits to be gained from the integration of the big five complementary and alternative professions.

(http://www.freshminds.co.uk/PDF/THE%20REPORT.pdf
Prince of Wales, Foundation For Integrated Health, Smallwood Report)

OECD report on Quality has illustrated the importance of appropriate training.
"Competence or capability, assesses the degree to which health system personnel have the training and abilities to assess, treat and communicate with their clients. There are many potential aspects of competence in this context, including technical competence as well as cultural competence. This dimension, in terms of its assessment, is assumed to be included in *effectiveness*."

(Health Care Quality Indicators Project, Conceptual Framework Paper, Kelley, Hurst; 23, OECD Health Working Papers, http://www.oecd.org/dataoecd/1/36/36262363.pdf)

The demographic issues facing Europe in health and social fields imply a natural evolution to: light regulation, (in a similar fashion to the evolution of the concept of Subsidiarity); allowing more market mechanisms to prevail, implementing the recommendations of Lannoy (European Parliament, Resolution on the status of non-conventional medicine, A4-0075/97; http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A4-1997-0075+0+DOC+PDF+V0//IT). All in the context of promoting evidence based health care along the lines of the House of Lords report (ref 2000). OECD and others have illustrated the benefits of deregulation in general.
Affirmative Community action is recommended to facilitate a regulatory environment conducive to stimulating new, innovative and emerging health care professions.

Question 2: what specific legal clarification and what practical information is required by whom (eg; authorities, purchasers, providers, patients) to enable safe, high-quality and efficient cross-border healthcare?

LEGAL CLARIFICATION

The rights and duties of the operators should be qualified – for example sick-notes should be recognised across borders with the minimum of hassle for citizens.

The concept of "diagnosis" as it applies to non-medical operators should be clarified across Europe. A medical diagnosis is not the same as a Chinese Medicine diagnosis or a chiropractic diagnosis, or a description of symptoms (syndrome).

Fiscal neutrality and scope of practice need to be clarified for patients receiving the same care in one country or another, regardless of the type of operator that treats the person – rather than the condition

Malpractice Insurance – is a problem for health care operators from emerging professions. For example a provider from a regulated country travelling to treat in a country where the same profession is not regulated, or that service is reserved to another profession faces uncertainty as to whether insurance coverage is valid. For example a UK registered chiropractor travelling to treat a patient for example with a UK sports team in Italy performs a diagnosis. "Diagnosis" is theoretically a "medical act" in that country. Does the UK insurance cover the professional?

PRACTICAL INFORMATION

The DG Internal Market SOLVIT mechanism is a positive tool. However clarification is needed in the application to the health sector.

The level of training and qualifications of the health care provider need to be readily recognisable and defined. The code of ethics and standards of practice and the use of an evidence based approach should be included in the definition of the provider.

Patient information should be communicated in a format readily legible across borders. Emerging professions should be actively encouraged to participate in EU eHealth programmes.

Guidelines should be actively promoted across Europe to harmonise expectations and care and raise standards through the spread of best-practice and bench-marking. Emerging professions should be involved in this process. The Low Back Guidelines are an excellent example of value added by Community Action.

Community Action can be constructive in aiding patients and professionals to identify, compare and choose between providers in other countries through the use and promulgation of guidelines, databases such as NHS Direct (http://www.nhsdirect.nhs.uk/), and accrediting agencies.

Question 3: which issues (eg: clinical oversight, financial responsibility) should be the responsibility of the authorities of which country? Are these different for the different kinds of cross-border healthcare described in section 2.2 above?

TELEMEDICINE

Practical issues have been raised in this field. A non-medical health care operator, in theory, cannot make an imaging diagnosis, for example a radiological diagnosis, in Italy. That same operator may well be registered in another country and qualified to perform such tasks in another country. If the operator is based in Italy, and performs the task via technological means in, say the UK, has an illegal act been committed in Italy? If the registered operator is in his own host country, yet performs the diagnosis in a country where he is not registered, has he broken the law, and in which country?. A myriad of variations on this theme put non-medical operators at a disadvantage in the health care market, raising costs to patients and society.

Similar considerations concern the recognition across borders of sick-notes, reports, for example radiological reports, and accident reports.

If health care operators could be recognised under the sectorial system these problems would be alleviated.

In the field of telemedicine, information on a EU database regarding the qualification of the operator could be compared across Europe.

The provider should be responsible for his malpractice insurance, so protecting the patient irrespective of where the service is performed or delivered.

Question 4: who should be responsible for ensuring safety in the case of cross-border healthcare? If patients suffer harm, how should redress for patients be ensured?

Professional associations should afford certification of members in the absence of national or European legislation. This is envisaged in the system of the “Common Platform”. A Europe-wide clearing house could screen qualifications and individuals. The European Council on Chiropractic Education and the European Chiropractors’ Union are examples of professional organisations that could make this work. These mechanisms promote quality and safety.

Harm should be redressed through contracts between the provider and the patient. Initial complaints would be dealt with by the professional association or regulatory body.

Question 5: what action is needed to ensure that treating patients from other Member States is compatible with the provision of a balanced medical and hospital services accessible to all (for example, by means of financial compensation for their treatment in 'receiving' countries)?

The care given needs to be optimised. The proposed action is the development and promulgation of guidelines to encourage efficacy, effective and cost-effective care. The encouragement of these principles will encourage competition and drive down costs, increase health, to the overall benefit of all member States Community Affirmative Action would promote representation of emerging professions in the working parties compiling guidelines.

A market mechanism needs to be elaborated to allow the movement of patients according to core-competencies and comparative advantage between countries. As in other markets, this will bring benefits to the economy and patients. .

Question 6: are there further issues to be addressed in the specific context of health services regarding movement of health professionals or establishment of healthcare providers not already addressed by Community legislation?

FURTHER ISSUES

Politics
Competition in Health; Regulation
Guidelines and Policy Making Committees
Fiscal Neutrality and Scope of Practice

1. POLITICS
The "Common Platform" in theory provides a system of recognition of new professions across Europe. The chiropractic profession was the first profession to present a dossier for recognition under the new Common Platform mechanism. However the case for moving forward was considered impossible due to the voting system. In essence, the weighting of votes according to population and according to numbers of countries makes it impossible for some small professions to contemplate Europe-wide recognition under the Common Platform system. A more streamlined approach, perhaps needs to evolve. Community Action could promote Member States to develop a system of mutual recognition for any profession, including health care professions "recognised, legislated and regulated" in at least five Member States.

Communication from the Commission to the European Parliament pursuant to the second subparagraph of Article 251 (2) of the EC Treaty concerning the common position of the Council on the adoption of a Directive of the European Parliament and the Council on the recognition of professional qualifications
Brussels, 6.1.2005, COM(2004) 853 final 2002/0061 (COD)

http://ec.europa.eu/internal_market/qualifications/docs/2001-newdir/com-2004-853_en.pdf

2. COMPETITION IN HEALTH.

Universal care is just. One draw back is that one profession, the medical profession is necessarily the gatekeeper and monopoly provider. The scope for conflict and inefficiency is evident. Competition in health care in Europe can be improved. The European institutions are invited to involve emerging professions in decision making and to establish a review of competition, along the lines of work done elsewhere.

Several issues are pressing and should be considered by the Commission when formulating health strategy.

REGULATION

"Free movement of health professionals is already largely addressed" – but not very satisfactorily when it comes to emerging and new professions and varying regulatory regimes:

.Regulation is justified for motives of asymmetry of information, externalities and "public goods". The regulated professions create rigidities in the evolution of the economy.

Product Market Regulation in the Non-Manufacturing Sectors of OECD Countries: Measurement and Highlights. Economics Department Working Papers No. 530. Conway, Nicoletti.
http://www.olis.oecd.org/olis/2006doc.nsf/43bb6130e5e86e5fc12569fa005d004c/754494cce33a9049c12572440031e2a0/$FILE/JT03219400.PDF

"Restrictions on entry and extensive regulation of other aspects of provider behaviour and organizational form can bar new entrants and hinder the development of new forms of competition. The scope and depth of regulation is also not universal; providers offering competing services are routinely subject to widely varying regulatory regimes"

Department of Justice, Federal Trade Commission
Improving Health Care: A Dose of Competition
http://www.ftc.gov/reports/healthcare/040723healthcarerpt.pdf

Competition in health was examined in depth by OECD Competition Committee Roundtable. "Enhancing Beneficial Competition in the Health Professions. 16 December 2005".
http://www.oecd.org/dataoecd/7/55/35910986.pdf

This is only alluded to in the DG Competition study of the liberal professions:

Report on Competition in Professional Services
European Commission, Brussels 9 February 2004, COM(2004) 83 final
Endnote 1:
"[1] The OECD is carrying out ongoing work on competition in professional services, including some of the professions not covered here."

Asymmetry of information between the provider and consumer was first described by Kenneth J. Arrow in 1963. He indicated regulatory regimes that ranged from full licence, certification to no regulation. The notion that health care providers are a special case due to the peculiarities of the asymmetry of information between the provider and the patient has been largely discredited. Several studies demonstrate that physician supply drives demand, both in North America and in Europe.

Arrow, Kenneth J. (1963). "Uncertainty and the Welfare Economics of Medical Care". *American Economic Review* **53** (5): 941-73.

Gruber, Jonathan and Owings, Maria, "Physician Financial Incentives and Caesarean Section Delivery" (November 1994). NBER Working Paper No. W4933. Available at SSRN: http://ssrn.com/abstract=245846

Public vs Private Health Care Services. Demand in Italy.
Daniele Fabbri, Chiara Monfardini, Department of Economics - University of Bologna.
http://www2.dse.unibo.it/wp/457.pdf

Public Health Insurance and Medical Treatment:The Equalizing Impact of the Medicaid Expansions

Gruber, Curie , http://econ-www.mit.edu/faculty/download_pdf.php?id=51

European Observatory on Health Care Systems Series
Regulating Entrepreneurial behaviour in European health care systems
Saltman, Busse, Mossialos, 2002

These studies and others undermine the "externalities" and "public goods" arguments for heavy handed regulation.

GUIDELINES AND POLICY MAKING COMMITTEES

Many medical and alternative procedures are still to be verified for efficacy and effectiveness. Health care is moving towards an evidence-based approach. Guidelines play an important part of this process. However politics and lobbies sometimes obstruct the formulation of objective guidelines. A study from 2001 considers 11 sets of national guidelines for the management of low-back pain. Findings are compared. Each set of guidelines purports to be evidence-based. A minority of four national guidelines – all of which lacked any chiropractic/osteopathic/physio therapy input on the guideline committees – did not recommend skilled spinal manipulation. The authors warn that "the makeup of the guideline committee may have a direct impact on the content of the recommendations"

The inclusion rather than the exclusion of important stakeholders can be seen as a necessary step in the development and implementation of guidelines. Similarly, emerging and new professions should be included in important policy making bodies such as the High Level Group on Health Services and Medical Care.

Koes, van Tulder, et al (2001) Clinical Guidelines for the Management of Low-Back Pain in Primar Care: An International Comparison, Spine 26(22): 2504-2512.)

FISCAL NEUTRALITY AND SCOPE OF PRACTICE

In addition to the judgements of the European Court of Justice quoted in the Consultation document, Legal Certainty has been further clouded in areas of scope of practice and fiscal neutrality following a recent judgment.

JUDGMENT OF THE COURT (Third Chamber), 27 April 2006 (*)(Sixth VAT Directive -? Article 13A(1)(c) -? Exemptions -? Provision of medical care in the exercise of the medical and paramedical professions -? Therapeutic treatments given by a physiotherapist and a psychotherapist -? Definition by the Member State concerned of paramedical professions -? Discretion -? Limits)

In Joined Cases C-?443/04 and C-?444/04, **H. A. Solleveld** (C-?443/04),**J. E. van den Hout-?van Eijnsbergen** (C-?444/04) http://www.bailii.org/eu/cases/EUECJ/2006/C44304.html

Question 7: are there other issues where legal certainty should also be improved in the context of each specific health or social protection system? In particular, what improvements do stakeholders directly involved in receiving patients from other Member States – such as healthcare providers and social security institutions – suggest in order to facilitate cross-border healthcare?

We suggest a Europe wide register of non-conventional health care operators and a database for consultation by stakeholders, to promote the exchange of information: by giving more responsibilities to professional associations.

Question 8: in what ways should European action help support the health systems of the Member States and the different actors within them? Are there areas not identified above?

ACCREDITATION AGENCIES

Areas not identified above include the proposed register of accrediting bodies to be created by ENQA. A register for accrediting bodies in the health sector is would go a long way to guaranteeing standards across Europe. It would be an elegant means for small profession and evolving professions to compensate for the difficulties in the Common Platform mechanism..

DEMOGRAPHICS AND MIX OF PROFESSIONS

Demographics, long-term ageing will cause increased strain on budget. There will be a shortage of health care professionals

The World Health Report 2006
http://www.who.int/whr/2006/whr06_en.pdf

It is important that the mix of health care professions includes the most effective and cost-effective health care operators. This will mean allowing new innovative professions to emerge, along the lines of Lisbon, and will mean allowing legacy professions to re-size and adapt via, to a certain extent, market forces

Demographics and the costs of technological innovation mean that a strategy involving affirmative action for knowledge innovation needs to be considered.

IMPACT ASSESSMENT

Commission decision bodies, the open system of communication should be expanded and opened up to include a wider range of health care professions

Question 9: what tools would be appropriate to tackle the different issues related to health services at EU level? What issues should be addressed through Community legislation and what through non-legislative means

TOOLS

The European Commission could create a new department along the lines of the WHO Traditional Medicine Strategy department.

WHO Department in Traditional Medicine and Complementary and Alternative Medicine (TM/CAM)
http://www.who.int/medicines/publications/traditionalpolicy/en/index.html
http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf

This department would be charged with accruing expertise and a database of information to help promote new, innovative professions and methods in the field of non conventional medicine. This department could also be run along the lines of an observatory for emerging professions in health care to avoid duplicating existing observatories.

A TASKFORCE ON OCCUPATION could be reinstated as a vehicle for Community affirmative action to promote new and emerging and innovative professions.
(Employment Strategy, Taskforce on Occupation.
http://ec.europa.eu/employment_social/employment_strategy/task_en.htm)

SOLVIT, the Internal Market department for facilitating mobility could be tuned to health care matters – holding for example workshops with regulators and members of the emerging professions.

ADDITIONAL REFERNCES

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