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To: SANCO-HEALTH-SERVICES-CONSULT
Cc: koenraad.verstraete@ugent.be
Subject: Health Service Directive

Please find the answers to Your questions on behalf of the Royal Belgian Radiological Society (RBRB) <http://www.rbrs.org/>

with kind regards,

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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?

The current cross-border healthcare between Belgium and neighbouring countries (e.g. the Netherlands and Great-Brittain) has no significant influence on local Belgian radiological healthcare.

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?

See answer on question 6.

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?

See answer on question 6.

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?

See answer on question 6.

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)?

See answer on question 6.

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?

The Royal Belgian Radiological Society supports the opinion of the UEMS – section radiology and the European Society of Radiology on this subject. Please find their opinion here.

a.. Dr Bruno Silberman, President UEMS Section of Radiology and Professor Nicholas Gourtsoyiannis, President European Society of Radiology have co-authored a joint statement Teleradiology in the European Union, March 2006.

Regulation of Teleradiologists:

A teleradiologist who reports on medical images of E.U, patients should:

a.. Be registered with the Medical Regulatory Body of each E.U. Member State where his/her patients reside.

a.. Should be on the Radiology Specialist Register of the Medical Regulatory Body of each Member State where his/her patients reside.

a.. Should have individual insurance/indemnity cover for each of the Member States where his/her patients reside.

a.. Must have a proper knowledge of the language(s) of each Member State where his/her patients reside, as required by the E.U. Qualifications Directive 2005.

a.. Should have a "Certificate of Current Professional Status" when applying for registration with a Medical Regulatory Body.

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a.. If providing teleradiology services for patients in another E.U. Member State, teleradiologists should be subject to the same regulatory requirements as local Radiologists. Such specific national medical regulatory arrangements may include revalidation, recertification, relicensure, annual appraisal.

a.. Teleradiologists should be subject to the regulations applied to locum doctors by the Medical Regulatory Body in each Member State where his/her patients reside.

Language Testing

Article 53 of the 2005 European Union Qualifications Directive states that "persons benefiting from the recognition of professional qualifications shall have knowledge of languages necessary for practicing the profession in the host member state".

The European Court of Justice ruled in case C-424/97 Haim II that the reliability of a dental practitioner's communication with his patients and with the administrative authorities and professional bodies were such that linguistic testing was justified.

Thus there is no E.U. legal barrier to linguistic testing of teleradiologists who report on medical images of patients in another Member State. There has never been any legal obstacle to testing linguistic competence of teleradiologists resident outside the E.U..

Linguistic competence has particular relevance to teleradiologists. If reporting imaging examinations at a distance by teleradiology, the clinical contact between the referring doctor and the reporting Radiologist is substantially reduced and the need for adequate linguistic competence is even more important for patient safety.

E.U. Healthcare Professionals Crossing Borders Agreement, 2005

Details of this may be accessed on:

<http://admin.uems.net/uploadedfiles/678.pdf>

This agreement is due to be implemented by the end of 2007 and will require E.U. Medical Regulatory Bodies to proactively exchange information when they have restricted a healthcare professional's right to practice because of a serious performance, conduct, health or criminal issue.

It also includes a "European Template for a Certificate of Current Professional Status". Teleradiologists registered in another E.U. Member State should be required to provide such a European Certificate from his/her Medical Regulatory Body before obtaining registration in another E.U. Member State.

Communication Requirements of Teleradiologists

A teleradiologist who reports medical images of E.U. patients must be required to be able to communicate directly with referring Radiology Departments and Clinicians in order to discuss the clinical background and unexpected diagnosis which may be relevant to the timely management of a patient. The contact phone number of the reporting teleradiologist should be provided on the report. A definitive report is mandatory with the electronic signature of the reporting teleradiologist. Teleradiologists who report medical images of E.U. patients should be subject to the same error feedback, clinical incident reporting, root cause analysis, audit and other forms of Clinical Governance as apply to local Radiologists.

Regulation of Teleradiology Providers

Teleradiology companies which provide reporting of medical images of E.U. citizens:

a.. Should be registered with the Healthcare Commission or equivalent in each E.U Member State where their patients reside, and be subject to its regulations/standards.

a.. Should be subject to the same Member State Regulations as apply to Medical Locum Agencies.

a.. At the conclusion of every doctor's employment, teleradiology providers should be required to make a brief standardised return to the relevant national Medical Regulatory Body.

a.. Teleradiology Providers should ensure that teleradiologists reporting imaging of patients in a particular Member State comply with the regulation revalidation annual appraisal and other national Clinical Governance Regulations of that Member State.

a.. When a teleradiologist changes employer or contracting organisation between relicensure cycles, the previous teleradiology provider should provide the new employer with a standardised record outlining the practitioner's current position in relation to the elements contributing to relicensure/recertification/revalidation.

a.. Clinical evaluation and data should be provided to the reporting teleradiologist.

a.. Teleradiology providers must comply with the requirements of the Euratom 97/43 Directive including Justification, and optimisation of imaging technique.

b.. Reports from Teleradiology Providers should be integrated with the patient's notes, electronic records, Radiology Information Systems and should be capable of review by clinicians and at multi disciplinary team meetings as easily as if the reports were generated locally.

a.. Teleradiology Providers should have close communication with the Radiology Departments who produce the medical images.

a.. Teleradiology Providers should ensure security and privacy of transmitted patient data comply with E.U. and National Directives.

a.. Teleradiology Providers should conduct regular user/clinician surveys. Robust audit procedures should be in place to check the quality and accuracy of reports and the overall therapeutic and clinical impact of the service.

b.. Teleradiology providers should have adequate medicolegal and insurance cover.

Dr Richard FitzGerald

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The Royal Wolverhampton Hospitals NHS Trust

U.K. Representative UEMS Section of Radiology and EAR POC.

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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?

See answer on question 6.

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?

See answer on question 6.

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?

See answer on question 6.

On behalf of the Royal Belgian Radiological Society

with kind regards,

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