

**Response to the European Commission
Community Action on Health Services**

The European Society of Radiology (ESR) and the European Union of Medical Specialists (UEMS) Radiology Section welcome the opportunity to respond to the discussion paper produced by the Commission on Community Action on Health Services in Europe.

While it is desirable that all European citizens have proper and timely access to health care, it is extremely important for them to be confident that the quality and standards of that health care is of a high level and similar regardless of the country providing the health services.

While the European courts have developed the principles of access without prior authorisation and proper reimbursement up to the level provided by their own system, it is important to recognise that health care is far more complex and open ended than one episode of surgery or emergency therapy and that inappropriate diagnosis and/or treatment may have long-term implications and costs not borne by the original providers of the health care episode.

The Commission acknowledge this in their introduction where they identify that one of the issues that require clarity is whether there are shared values and principles for health services on which citizens can rely throughout the EU. The balance of regulation of member state systems and free movement of services and providers and how patients and professionals can identify, compare and choose between providers in different countries also needs to be addressed.

The Commission identify four possible types of cross border healthcare: Radiology is relevant to all four types.

- Cross border provision of services including telemedicine services and remote diagnosis: Teleradiology services are already being provided in member and non-member states for patients in other member states.
- Use of services abroad: Patients from one member state may use imaging and interventional radiological services primarily or as part of a treatment package in another member state.
- Commercial healthcare and imaging service companies are providing radiological services in one member state for patients in other member states through teleradiology.
- Mobility of health professionals: Radiologists are moving temporarily from one member state to another to provide services.

The European Society of Radiology (ESR) and the UEMS Radiology Section therefore support the Commission and applaud their statement that: 'Future sustainability of healthcare and social security systems will require efforts to improve efficiency whilst respecting universal access to high quality health care which is financially sustainable and provides equity and equality'.

As recognised in the document, cross-border healthcare where the nearest hospital for citizens is in a neighbouring member state, and the provision of some specialist services is not sustainable in a small country are legitimate scenarios for this process.

However, the provision of routine diagnostic evaluations far removed from the patient and with no significant opportunity for consultation between radiological diagnostician, patient and referring physician does not fall into this category and is a major concern of the European Society of Radiologists and the UEMS Radiology Section.



The Commission confirm that cross-border health care encounters problems due to incompatible rules between the countries concerned and the lack of a transparent legal framework and European structure for cooperation.

There is also a major potential problem of protection of the patient's data which the Commission have also rightly raised. In particular, the Commission also confirms that patients prefer to be treated near their homes. This also applies to diagnosis. There is a common fallacy that radiological imaging simply involves reading a set of images and producing a report. However, the radiologist undertakes a number of tasks many outlined in the Euratom 97/43 Directive including:

- Ensuring full clinical information on the patient is available
- Discussing the clinical problem with the clinician
- Choosing and justifying the most appropriate type of investigation from the many available
- Monitoring the examination
- Reporting the examination
- Discussing the results with clinicians, multi-disciplinary teams and often the patient
- Suggesting and undertaking further investigations
- Performing minimally invasive therapeutic procedures

These tasks require a wide medical knowledge, certification of specialist training in the speciality, a close working relationship with clinical colleagues and a thorough knowledge of the language of the patients and their clinical carers.

It is also unclear as the Commission point out that data regarding the economic, social and health impacts of cross-border healthcare for citizens is unclear and will required careful analysis.

Question 1:

Teleradiology provision is advancing rapidly in a number of member states. Many are providing diagnostic e-networks within their own countries which have been shown to be valuable especially for widely distributed low density population areas and for specialist consultation. However, some member states are commissioning cross-border radiological services in increasingly large numbers which is beginning to have a significant local impact and the quality and financial sustainability is far from clear as well as the legal structure and standards.

Question 2:

Identifying the competent authorities and their responsibilities

The Commission identify this as a key concern in particular identifying the authority responsible for ensuring the quality and safety of health services provided to people from other member states but also the member state from which the patient originates. This is particularly important when the authorities of a member state may be purchasing the cross-border healthcare services for individual patients as in the case of teleradiology services.

Question 3:

Which issues are the responsibility of the authorities of which country?

The Commission rightly identify the need for clarity about who is responsible for ensuring patient safety in cross-border healthcare. They also highlight the importance of following up errors and ensuring that patients are not put at further risk.

This problem is particularly pertinent to radiological services as imaging examinations undertaken in an EU member state can now be read in any other member state or indeed any other country in the world. At present there is no control of this process. It is the view of the ESR and the UEMS Radiology Section that for the safety of the EU patient the teleradiologist who reports on the imaging examination:



- Should be registered with the medical regulatory body with each EU member state of residence of all patients for which he/she provides reports;
- Should be on the specialist register for radiology of the medical regulatory body of each EU member state of residence of all patients for which he/she provides reports;
- Should have individual insurance/indemnity cover for each member state of residence of all patients for which he/she provides reports;
- Must have a proper knowledge of the language(s) of each member state of residence of all patients for which he/she provides reports as required by the EU Qualifications Directive 2005;
- Should be subject to the same regulatory requirements, including CME, revalidation, recertification, relic ensure and appraisal of each member state of residence of all patients for which he/she provides reports.

Question 4:

Who should be responsible for ensuring safety in the case of cross-border health care? If the patients suffer harm, how should redress for the patient be ensured?

- It must be the responsibility of national authorities to ensure safety of the patient in cross-border radiological services particularly teleradiology, where the patient has no contact with the doctor providing the service and who may be working part-time for a number of providers of teleradiology services.
- Unless there is a robust means of legal responsibility by the providers of teleradiology services and the individual reporting doctor, it will be almost impossible for the patient to be redressed for suffering harm by an erroneous report.
- It is also important that there is a proper system of audit of radiological reports from teleradiology providers which entails a proper feedback mechanism from the clinicians for whom the reports are provided. This

requires direct relationship between the radiological services where the patient was imaged the referring clinician and the teleradiology provider.

- A record of discrepancies in the reports and outcome should also be kept for discussion and analysis.

Question 5:

The European Society of Radiology (ESR) and the UEMS Radiology Section would only comment that the provision of cross-border services particularly teleradiology should not cause a decline in the service provided in the purchasing member state due to the provision of teleradiology at low cost in states with a marked differential level of remuneration compared to the purchasing state. It is important that the safety of the patient and the standard of care to which the patient is entitled are not sacrificed to financial expediency by the purchasing authorities.

Question 6:

Issues regarding movement of health care professionals or establishment of health care providers not already addressed by community legislation.

There should be registration of cross-border diagnostic imaging, and in particular, teleradiology providers. The following should apply to teleradiology companies which provide reporting of medical images to EU citizens:

- They should be registered with the health care authorities in every member state for whom they provide services to patients and be subject to their regulations/standards.
- They should be subject to the same member state regulations as apply to medical locum agencies.
- A standardised return of information on every doctor employed should be made to the relevant national medical regulatory body.



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- They should ensure that radiologists working for them comply with the revalidation, appraisal and clinical governance requirements of the member state for whom they provide services.
- Standardised returns should be made between employers when a teleradiologist changes employer regarding the teleradiologist's registration and revalidation status in the member states for which a service is being provided.
- They must comply with all the provisions of the Euratom 97/43 Directive.
- Their reports must be integrated with the patients other notes and be capable of review with the patient's clinicians and at multi-disciplinary meetings.
- They should ensure security and privacy of transmitted patient data complying with EU and National Directives.

Question 9:

The European Society of Radiology (ESR) and the UEMS Radiology Section consider that a robust framework of regulation of cross-border health care provision is required across Europe to protect the safety and standard of care that EU patients have a right to expect. This is particularly the case in e-health and especially in teleradiology where the patient has no contact and the clinician responsible for their care little or no contact with the provider of the service that the patient requires.

- This degree of regulation will only be achieved through a directive requiring member states to ensure that the patient, the centre where the images are undertaken, the referring clinician and the teleradiology services are in close contact and responsible to each other for a high standard outcome.
- The companies providing services must be properly registered and comply with the regulatory requirements of the countries for which they are providing services,



- The individual radiologists providing the reports must be fully qualified, registered with the regulatory authorities, and comply with the continuing training and revalidation requirements of the country for which they are providing reports.
- There must be a robust method of feedback and audit of the results of the teleradiologists and teleradiological service and clear lines of legal responsibility which will allow patients to receive compensation without great effort if they are inappropriately harmed.

The teleradiologist providing a service must speak the language and must liaise with the clinicians of the patients for whom they are providing a report.

Finally the European Society of Radiology (ESR) and the UEMS Radiology Section would like to thank the Commission for giving them the opportunity to contribute to the Commission's deliberations on this vital matter.

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