ESR Response

European Commission Consultation on the PROFESSIONAL QUALIFICATIONS DIRECTIVE (2005/36/EC)

March 2011

Introduction

The European Society of Radiology (ESR) is an apolitical, non-profit organisation, dedicated to promoting and coordinating the scientific, philanthropic, intellectual and professional activities of Radiology in all European countries. The Society's mission at all times is to serve the health care needs of the general public through the support of science, teaching and research and the quality of service in the field of radiology. The ESR is the European body representing the radiology profession with over 52,000 individual members and acts as the umbrella organisation of all national radiological societies in Europe as well as Europe's subspecialty organisations in the field of radiology. The ESR is registered in the European Commission's transparency register.

The ESR fully supports the free movement of radiologists within the EU member states on condition that quality of care and patient safety are adequately secured. The ESR also welcomes the current revision of the Professional Qualifications Directive (2005/36/EC), as it allows taking into account recent developments and advances in medical technology and radiological practice (in particular with regard to teleradiology), giving priority to ensuring utmost patient safety, as well as emphasising the importance of continuing professional development and its documentation towards the competent authorities.

The ESR has carried out a number of surveys that demonstrate that radiology education and training still differs significantly within the EU member states. A survey carried out in 2004[1] demonstrated the existence of a wide spectrum of diversity in terms of requirements, training schemes, appraisal and professional evaluation between the various countries throughout Europe. One of the key aims of ESR has been to support the harmonisation of training schemes in Europe in order to bridge this gap.
In line with its mission to harmonise European training programmes, the ESR has revised its **European Training Charter for Clinical Radiology** and introduced the **European Diploma in Radiology**, which are presented in more detail at the relevant sections of the following response.

Given the developments of the radiology profession over the past years, the ESR requests that **the name of the discipline in the Directive be changed from "Diagnostic Radiology" to "Radiology"**, as the profession nowadays comprises both diagnostic and interventional procedures. In order to keep pace with the increasing complexity of medical imaging and growing training needs, **the ESR requests that the minimum years of training laid down in the Directive be increased from four to five years.** This will ensure that the Directive is in line

[1] http://www.myesr.org/html/img/pool/ESR_brochure_05.pdf

with ESR's efforts to harmonise training curricula and to ensure equally high standards of training throughout Europe.

The ESR responds to this EC Consultation as an umbrella organisation of all European national radiological societies and focuses on a selection of questions of relevance to the radiology profession. The ESR response has been aligned with the European Union of Medical Specialists (UEMS).

The ESR would like to take the opportunity to declare its interest and willingness to provide its expertise as a European professional organisation to the European Commission in regard to the priorities and challenges perceived for the radiology profession (as laid down in Article 59 of the Directive).

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According to the Directive 2005/36/EC, *Diagnostic Radiology* is a medical specialty falling under the automatic recognition procedure for member states observing the minimum training requirements as defined in Annex V of the Directive (*minimum training of 4 years*).

As outlined in the introduction, **the ESR requests a name change of the discipline into "Radiology", as the current practice of radiology encompasses both the diagnostic use of imaging and image-guided interventions**. In addition, **the ESR requests that the minimum duration of training in radiology should be increased to 5 years** in order to be compliant with the ESR – European Training Charter for Clinical Radiology and to reflect the increasing complexity of the discipline. 95% of the EU member states already apply a 5-year training curriculum.

Question 2: Do you have any suggestions for the simplification of the current recognition procedures? If so, please provide suggestions with supporting evidence.

The ESR would like to emphasise that any simplification of the Directive 2005/36 Recognition of Professional Qualifications must not be to the detriment of patient safety, quality and transparency. It is important that there is a smooth and efficient channel of communication between the competent authorities in the EU member states in order to ensure accurate recognition procedures for radiologists seeking cross-border employment in the interest of patient safety. In addition, the **European Diploma in Radiology** (as recently introduced by the ESR according to its European curriculum), supplementing the national qualification, could serve as an additional qualification criterion and quality label, facilitating cross-border movement of radiologists.

Question 3: Should the Code of Conduct become enforceable? Is there a need to amend the contents of the Code of Conduct? Please specify and provide the reasons for your suggestions.

The ESR welcomes the administrative guidance provided by the Code of Conduct to competent authorities on a non-binding basis, offering examples of best, acceptable and unacceptable practices. However, it appears important to raise awareness of the existence of the Code of Conduct and to allow regular scrutiny and updating of the document in consultation with European professional associations. In particular the current guidance in regard to language skills needs to be looked at carefully in terms of ensuring utmost patient safety. Communication with patients and referrers is an integral and vital part of the daily work of radiologists and migrant radiologists need to have appropriate skills in the language of the host country in order not to jeopardise patient safety and quality of care.
Teleradiology needs to be given special attention in the context of the Code of Conduct, as it is important to provide good practice examples for electronic healthcare, ensuring that teleradiology adheres to the same professional medical quality and safety standards as traditional radiology. Radiologists providing teleradiology services need to be fully registered specialists and the potential issue of ghosting needs to be properly addressed.

Question 6: Do you see a need to include the case-law on "partial access" into the Directive? Under what conditions could a professional who received "partial access" acquire full access?

Partial access should not be applicable to the radiology profession, as any radiologist needs to be fully qualified and thus merit full recognition by the host country competent authorities.

Question 7: Do you consider it important to facilitate mobility for graduates who are not yet fully qualified professionals and who seek access to a remunerated traineeship or supervised practice in another Member State? Do you have any suggestions? Please be specific in your reasons.

The ESR welcomes the idea to facilitate mobility for radiologists in training across the European Union, provided there is a robust structure in place that ensures adequate recognition of training time spent in another member state by the trainee's country of origin, although the ESR is aware that there might not be consensus on this issue at member-state level.
The European Training Charter for Clinical Radiology as well as a robust log-book keeping track of the individual's training could serve as a reference in this process.
Currently the possibilities of exchange for radiologists in training are limited in many EU member states, thus creating an obstacle to the freedom of movement.

*Question 11: What are your views about the objectives of a European **professional card**? Should such a card speed up the recognition process? Should it increase transparency for consumers and employers? Should it enhance confidence and forge closer cooperation between a home and a host Member State?*
Question 12: Do you agree with the proposed features of the card?
Question 13: What information would be essential on the card? How could a timely update of such information be organised?
Question 14: Do you think that the title professional card is appropriate? Would the title professional passport be more appropriate?

The ESR fully endorses enhancing transparency with the ultimate goal of guaranteeing patient safety, as well as reducing the administrative effort related to the recognition procedures.
The ESR welcomes the introduction of a European professional card for the medical specialty of radiology, provided it would contribute to facilitating the administrative procedures regarding qualification recognition and a harmonisation of training standards throughout EU member states.
In parallel with the introduction of the card, it might be efficient to refine and raise awareness on existing tools and initiatives in this area, such as the Internal Market Information System (IMI), and to make the use of such tools mandatory also for health professions and for all EU member states. For the sake of transparency, patients should have the right to request information from such tools.

The ESR would be willing to offer its advice and support in developing the card concept. In terms of title, the ESR would prefer the term “professional passport”, as it seems to more explicitly reflect the cross-border context. The introduction of such a card needs to be accompanied by adequate preventive measures against misuse and fraud and needs to be fully compliant with data protection legislation. The ESR agrees with the features of the card proposed in the consultation document and sees a potential benefit in terms of ensuring high quality of care for practitioners of eHealth, by preventing cases of ghosting and ensuring that teleradiologists fulfil the same high training and quality criteria as non-radiologists.

In view of harmonising radiological standards throughout Europe, the ESR launched the **European Diploma in Radiology** **(EDiR)** as an additional qualification, supplementing national board certificates, in March 2011. The examination provides an objective test of knowledge (not of competence) in general radiology at a standard to be expected at the end of 5-year training as outlined in the ESR curriculum. In the context of medical migration, this examination is intended to facilitate procedures by providing an ESR-endorsed qualification to confirm proof of knowledge supplemental to any national qualifications. The format of the ESR diploma examination is set for knowledge after 5 years of training.

The European Diploma represents an additional pan-European quality label in radiology training endorsed by the UEMS. The ESR would welcome recognition of the diploma by the European Commission, as this would add value and visibility to the training harmonisation efforts of the ESR. There is a clear need for European diplomas endorsed by the European Commission and recognised by the member states as a supplemental proof of fitness to practice throughout the European Union.

Question 15: What are your views about introducing the concept of a European curriculum – a kind of 28th regime applicable in addition to national requirements? What conditions could be foreseen for its development?

The ESR highly welcomes the concept of a European curriculum for radiology training, as one of its key aims is to support the harmonisation of training schemes in Europe in order to ensure equally high standards of training and ultimately patient care throughout Europe.

The ESR has revised its **European Training Charter for Clinical Radiology**, reflecting the ever increasing scope and complexity of radiology and ensuring compliance with the EC EURATOM regulations regarding radiation protection of patients and workers. New elements in the revised 5-year curriculum include specific sections dealing with communication skills, molecular imaging, good radiology report writing, multidisciplinary conferencing, trainee logbook procedures and continuing medical education (CME). The ESR curriculum is supplemental and exists in parallel to national training programmes and has no intention to replace them. The Charter is considered a living document and is continuously updated by the ESR. The latest update was published in February 2011.

The ESR intends that this curriculum document will provide a template for radiology trainees and educators, with the long-term aim of harmonising radiology training and enhancing the quality of radiological care for patients throughout Europe. It is hoped that its existence will be helpful to national societies in their discussions with governments and other regulatory authorities. It is intended to assist individual national societies in their aims of promoting high-quality radiological education nationally, and in their efforts to ensure good radiological patient care through the encouragement of a structured clinical radiological training period of a minimum of five years throughout all European countries. The revised charter continues to outline a five-year (three + two) training period, including basic training over the first three years and flexible subspecialty interest training during the last two years.
Several member states currently follow the European Training Charter for Clinical Radiology.

The ESR would highly welcome endorsement of the European curriculum by the European Commission (cf page 12 in the consultation document), which would add significant visibility and leverage.
The ESR European Training Charter for Clinical Radiology is endorsed by the European Union of Medical Specialists (UEMS) and has been incorporated into the UEMS Training Charter.

Question 18: How could the current declaration regime be simplified, in order to reduce unnecessary burdens? Is it necessary to require a declaration where the essential part of the services is provided online without declaration? Is it necessary to clarify the terms "temporary or occasional" or should the conditions for professionals to seek recognition of qualifications on a permanent basis be simplified?

The ESR is of the opinion that high quality care and patient safety needs to be the key priority, no matter whether healthcare professionals seek cross-border employment on a long-term basis or whether they move to another member state for temporary and/or occasional practice. The ESR would welcome a clarification from the European Commission regarding the definition of "temporary/occasional".
If the radiologist's qualification is fully recognised in a member state that follows the European curriculum as defined by ESR and if the radiologist's language skills are adequate, the ESR has no concerns regarding an administrative simplification for temporary/occasional practice.
However, there must be no difference in regard to electronic (teleradiology) and non-electronic practice of the radiology profession, thus the same regulatory requirements need to apply for teleradiology.

EHealth is a new and promising technology that provides not only tremendous progress in healthcare, but could also lead to potential threats to the safety of patients, given the fact that ICT solutions are applied to transfer health data, as well as the fact that healthcare services are often provided in another Member State (or even in third countries), which implies the need for clear regulation of quality and safety aspects. The ESR deeply regrets that eHealth regulations have been downscaled significantly in the Cross-border healthcare Directive and is concerned that eHealth and in particular teleradiology are currently not properly regulated at EU level.

The ESR strongly advocates that the responsibility for the quality and standards (regulation) of teleradiology and telemedicine should remain with the member state of affiliation in the interest of utmost patient safety. It should therefore be the responsibility of the member states to extend their national medical regulation to telemedicine and teleradiology (national registration, medical language skills, CPD achievements).

Question 19: Is there a need for retaining a pro-forma registration system?

Pro-forma registration of the migrant radiologist with the professional register of the host country is welcomed by the ESR, as it facilitates the application of disciplinary provisions in the host country. It is the understanding of ESR that the majority of member states require this for health professions and ESR sees no need to abandon this practice as it contributes to patient safety.

Question 22: Do you see a need to modernise the minimum training requirements? Should these requirements also include a limited set of competences? If so what kind of competences should be considered?

In line with its mission to harmonise European training programmes, the ESR has revised its **European Training Charter for Clinical Radiology**, reflecting the ever increasing scope and complexity of radiology. New elements in the revised 5-year curriculum include specific sections dealing with communication skills, molecular imaging, good radiology report writing, multidisciplinary conferencing, trainee logbook procedures and continuing medical education (CME). Special attention is also given to radiation protection training and related CPD, in order to ensure utmost safety of patients and workers.
The ESR – European Training Charter for Clinical Radiology is publicly accessible on the ESR website and lists the set of competences considered essential for the radiology profession and follows an output-based approach.

The ESR requests that the minimum years of training in radiology as listed in Annex V of the Professional Qualifications Directive (2005/36/EC) should be raised from four to five years in order to reflect the ever increasing scope and complexity of radiology and in order to be compliant with the ESR – European Training Charter for Clinical Radiology.

The ESR supports the EC's demand for increased transparency regarding the training contents between member states and carries out regular surveys among the national radiological societies in order to keep a log-file of the current training schemes for the radiology profession.

The ESR- European Training Charter for Clinical Radiology should guide member states in aligning their national training requirements to ensure equally high standards in training.
It is of great importance that the regulatory authorities of all EU member states cooperate and that easy cross-referencing takes place among the bodies responsible for radiological education and licensing regulatory authorities, teaching centres, local hospital administrations etc.

In order to improve and harmonise the standards of radiology training in Europe, the ESR has established the **European Training Assessment Programme (ETAP)** as a subcommittee of the Education Committee of ESR. ETAP was founded in 2001 as a joint initiative with the UEMS Radiology Section and is currently funded equally by the ESR and the UEMS. The programme provides institutions that offer postgraduate radiology education with objective assessment of their training programmes by external assessors nominated by the ETAP Subcommittee and develops assessment systems and guidelines for use by postgraduate education authorities at a national level. Assessment is voluntary and does not constitute a regulatory process.
The ESR would like to offer its expertise to the European Commission in order to discuss the assessment programme further with a view to potentially applying the system to other professions in the health sector.

Question 27: Do you see a need for taking more account of continuing professional development at EU level? If yes, how could this need be reflected in the Directive?

The ESR Training Charter for Clinical Radiology contains clear provisions on continuing education and should be interpreted in the context of understanding the seamless transition from training to lifelong continuous medical education (CME) and continuous professional development (CPD). The ESR strongly supports that an appreciation of the concept of life-long-learning should be instilled at an early stage of training and be enshrined in the revised Directive.
The ESR – European Training Charter for Clinical Radiology strongly supports a record of achievement and competence and demands that a written or e-log book of activity during training as well as of CPD activities should be maintained. This should provide a formal validated record of competencies achieved and examinations performed and should form an integral part of regular assessments of satisfactory training.

The ESR is of the opinion that the revised Directive should also include a provision that competent authorities shall be entitled to request documentation about CPD activities.

Question 28: Would the extension of IMI to the professions outside the scope of the Services Directive create more confidence between Member States? Should the extension of the mandatory use of IMI include a proactive alert mechanism for cases where such a mechanism currently does not apply, notably health professions?

In the interest of patient safety, the ESR supports the introduction of a legal duty on all medical regulators to share registration and fitness to practise information with other regulators in Europe in the revised Directive (proactive alert mechanism). Existing data protection issues should be resolved in order to facilitate the creation of such an alert system.

All competent authorities in EU member states should be obliged to use the IMI system in order to exchange information on professional malpractice.
These regulatory requirements are considered essential also for the practice of teleradiology. The EU member states shall be obliged to ensure that the use of e-Health and other telemedicine services adhere to the same professional medical quality and safety standards as those in use for non-electronic healthcare provision. In addition, they should offer adequate protection to patients, notably through the introduction of appropriate regulatory requirements for health professionals similar to those in use for non-electronic healthcare provision.

Question 29: In which cases should an alert obligation be triggered?

In the case of radiology an alert obligation should be triggered in cases of: malpractice, unethical professional behaviour (such as ghosting of teleradiology reporting) etc.
The list is non-exhaustive and should be elaborated further.

Question 30: Have you encountered any major problems with the current language regime as foreseen in the Directive?

Article 53 of the Directive clarifies that professionals should have the level of knowledge of the national language that is necessary for exercising the professional activity in question. Any language requirement should be justified and proportionate, in view of the activity a professional actually wishes to carry out. Recognized professionals are entitled to attest their language knowledge through any means of proof. Language testing is only allowed in exceptional cases (e.g. speech therapist).
Currently it is the responsibility of the employer to ensure the migrant professional has sufficient language skills.

With regard to the radiology profession, communication with patients and referrers is an integral and vital part of the daily work of radiologists and migrant radiologists need to have appropriate skills in the language of the host country in order not to jeopardise patient safety and quality of care. It is important that radiologists are able to communicate appropriately with patients and their colleagues. The competent authorities should be able to also consider the language aspect when assessing the fitness to practise of migrant radiologists.

Language skills are a particular issue in teleradiology, as the clinical contact between referring clinicians and the radiologist is considerably reduced. Therefore communication needs to be structured and reporting terminology harmonised, and adequate language skills are vital. Inadequate language skills could represent a potential source for errors during reporting and thus jeopardise patient safety.

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