



Review of the Professional Qualifications Directive (2005/36/EC)

EPF Position Statement

June 2012

The European Patients' Forum is a not-for-profit, independent organisation and umbrella representative body for patient organisations throughout Europe. We advocate for high-quality, patient-centred, equitable healthcare for all patients across Europe. EPF currently represents 54 patient organisations, which are national patients' platforms and chronic disease-specific patient organisations at EU level. Together they reflect the voice of an estimated 150 million patients affected by various chronic diseases.

Why the proposal to review the professional qualifications directive matters for patients

Ensuring that healthcare professionals have the right training, and are fit to practice when they move from one EU Member State to another, is of crucial importance for patient safety and quality of care.

Healthcare professionals are the most mobile category among the regulated professions in the EU,¹ and their mobility is likely to increase in future. Mobility of the health workforce is an opportunity for healthcare professionals to gain valuable experience and learn from different health systems. It can help balance workforce shortages and surpluses, and lead to exchange of good practices on quality of care across Europe.

But there is also a potential risk to patient safety and of increased health inequalities if the standards of quality of healthcare are not assured. The provisions which apply to the healthcare sector within the Professional Qualifications Directive have a direct impact on patient safety and are of great concern for the patient community.

EPF strongly believe that patients play a key role in identifying healthcare service needs, including the appropriate skills and competences needed for high quality healthcare: patients live with their disease every day, learn to manage it, and to navigate the health system to get the care they need. Their experiential knowledge can help to identify gaps in the system, and contributes to finding solutions that 'work' from an end-user perspective and are cost-effective. The patient perspective is therefore essential to address the

¹ http://ec.europa.eu/internal_market/qualifications/docs/news/20110706-evaluation-directive-200536ec_en.pdf, p. 42

challenges facing the EU health workforce and need to be taken into account in relevant policies including the implementation of the Action Plan².

Methodology of the EPF position statement

This position statement was developed on the basis of the key issues identified by EPF's membership in our responses to the European Commission's two public consultations on the review of Directive 2005/36/EC³ and with input from the EPF's Policy Advisory Group and Board.

This statement focuses only on those aspects of the proposal amending Directive 36 that relate to healthcare professions.

1. Improving patient safety: provisions for patient protection

EPF believes that the principles of patient safety and quality of care should be at the core of the revision of this Directive. Downgrading the education and requirements for healthcare professionals' mobility, far from being of benefit to the Single Market, would represent a risk that would undermine all the on-going efforts to improve patient safety and quality of care across the EU.⁴

The Commission puts forward three main measures to improve patient protection. While we warmly welcome these, we believe they need to be further clarified, and complemented by additional provisions to improve transparency and ensure patient safety.

1.1. Alert mechanism – Article 1(42)

EPF welcomes the proposal to establish a proactive alert mechanism between competent authorities of Member States. Under this system, authorities would be required to share with all other Member States' competent authorities information about the identity of a healthcare professional⁵ who has been prohibited by courts or national authorities from practicing the profession on the territory of that Member State, even temporarily.

In EPF's view this is a step forward in European cooperation on patient safety. **We strongly support the proposal to make the use of the IMI system compulsory.** This is necessary for the functioning of the alert mechanism, as well as for cooperation in cross-border healthcare.

For better patient safety, the competent authorities should also be obliged to warn each other **when a fake diploma come to their attention**, as fraud in this area present major risks for patients. In Finland, two fake doctors were discovered recently, both of whom had falsified diplomas from abroad; the national supervisory authority is being investigated for

² http://ec.europa.eu/dgs/health_consumer/docs/swd_ap_eu_healthcare_workforce_en.pdf

³ Available [here](#) (March 2011) and [here](#) (September 2011)

⁴ See the joint statements between EPF and the European Public Health Alliance (EPHA), available [here](#) and [here](#)

⁵ Note that this would apply to healthcare professionals that are benefitting from automatic recognition- for other healthcare professionals it is the existing alert mechanism of the service directive that would apply

possible negligence in its supervision of the medical credentials of doctors with qualifications obtained abroad.⁶

EPF also calls for **more transparency towards patients and the general public** concerning health professionals' fitness to practice. In our view genuine transparency needs to be extended to the public to ensure public trust and confidence in the system. The Directive should require the development of easily accessible public information platforms in all Member States. Such platforms already exist in certain Member States.⁷

1.2. Increased transparency between Member States on continuing professional development – Article 1(17)

1.2.1. Continuing professional development

Continuing professional development (CPD) is training for health professionals that ensures their knowledge and skills are up to date throughout their working life, and enables them to maintain and continuously improve their performance and meet professional standards. Currency of knowledge and up-to-date skills are key to enable health professionals to provide safe, high-quality care. CPD is also essential to adapt skills to the use new solutions, such as eHealth and ICT-supported tools, with confidence.

CPD requirements are set by each Member State, but there is currently no obligation for a Member State to have a CPD system in place. **EPF strongly supports the proposal that Member States should report on the CPD arrangements** related to healthcare professionals benefitting from mutual recognition in their countries to the Commission, which will make this information publicly available. Exchange of information is an important step that can lead to a better understanding of the needs for continuing professional development and in the long term to a higher quality of CPD in the European Union. However, the legislation should go further: **It should be mandatory for Member States to have in place a system of CPD (or equivalent) for health professionals.**

1.2.2. Fitness to practice – temporary mobility vs. permanent establishment

EPF considers that there is currently a gap in the Directive that can put patients at considerable risk and needs to be addressed.

For temporary mobility, Member States can require “an attestation certifying that the holder is legally established in a Member State for the purpose of pursuing the activities concerned and that he is not prohibited from practising, even temporarily, at the moment of delivering the attestation.” (Article 7b, Directive 2005/36/EC) Yet this obligation does not apply for longer-term mobility (i.e. permanent establishment).

EPF believes that an attestation should always be required, whether for permanent or temporary mobility. Furthermore, the Directive should require that the competent

⁶ <http://www.hs.fi/english/article/Fake+doctor+may+have+treated+thousands+of+patients+in+Southern+Finland+/1135269840260>;

<http://www.hs.fi/english/article/Supervisory+authority%E2%80%99s+actions+in+fake+doctor+case+spark+new+criminal+investigation/1329104227534>

⁷ Hungary: <http://www.eti.hu/eti/fooldal/3354>

Ireland: <http://www.medicalcouncil.ie/Public-Information/Check-the-Register/>

authorities should **only deliver such an attestation if the healthcare professional is fully up to date with the national CPD requirements**. This should be explicitly mentioned in the attestation.

1.3. Control of health professionals' language skills – Article 1(38)

Adequate knowledge of the language is crucial to effective communication with patients and colleagues – and therefore to patient safety and quality of care. It is therefore a positive development that language skills are addressed in the Commission's proposal.

EPF agrees that the provisions concerning language testing should be more stringent than is currently the case for all professions with patient safety implications. It should be clarified what "patient safety implications" means: from a patients' perspective this would not be limited to professionals who are in direct contact with patients, but also others such as lab technicians, for whom clear and accurate communication is a crucial safety issue. The level and nature of language requirements (e.g. verbal, written, understanding or interpreting text) would obviously be different for different professional roles. These requirements should be clarified.

However, EPF is concerned that in the legislative proposal the language checking remains optional, and the "who" and "how" of testing remains very unclear, leaving room for different interpretations by Member States that could put patients at risk.

While we understand that the approach to language testing should be proportionate, we believe patient safety should be the highest priority. Therefore, EPF's view is that health professionals' language skills should be ensured before they first start practising. The Commission is concerned that duplication of testing of health professionals could become a barrier to mobility. In EPF's view, "double-testing" is not the first and foremost concern of patients – safety is.

EPF recommends that the question of recognition of qualifications should be separated from the question of a licence, registration or authorisation to practice. The former could take place prior to the verification of language skills, but the latter must not. EPF would support a two-step process whereby testing health professionals ability to communicate could be done after recognition of the qualification, but before any registration or granting of a licence to practice.

EPF also recommends that "national competence requirements" should be developed and monitored by the national health system – even if in practice the tests could be delivered through employers. This would avoid divergence in criteria for testing.

National competence requirements should include knowledge of common lay terms for medical events, the way patients speak, and the kind of language they understand.

National health systems should consult patient organisations regarding language requirements and criteria for testing of all (categories of) health professionals with patient

safety implications. EPF consider this wider consultative role would be more appropriate and feasible than the current proposal.⁸

2. Other provisions with a relevance for healthcare and patients

Besides the provisions mentioned above, there are some other areas in the draft Directive that also have a potential impact on patient safety and quality of care. EPF calls for the European Commission, the European Parliament and the Council to take into consideration the patient perspective on the following provisions.

2.1. Mobility of graduates – Articles 1(1) and 1(39)

EPF does not support the extension of the scope of the Directive to encompass the recognition of the traineeships of graduates that are carried out in another Member States. A distinction between graduates who have not yet completed their training and fully qualified healthcare professionals is necessary: for legal clarity the Directive should continue to apply only to fully qualified professionals.

2.2. The European Professional Card – Article 1(5)

EPF is generally supportive of the European Professional Card, if it can be shown to offer added value for health professionals and competent authorities, and to improve patient safety.

However, **we are concerned that the provision in para. 5 of new Article 4d concerning “tacit recognition” of qualifications may undermine patient safety.** If the competent authority cannot provide an answer within the timeframe of one or two months, the qualification would be automatically recognised. In EPF’s view, competent authorities should be allowed enough time to assess applications as thoroughly as needed, regardless of the format in which the application is provided.

Furthermore, patients should be reassured that regardless of which procedure is used, the authorities review an equivalent level of information concerning the applicant.

Finally, **having the EPC should not free professionals from the need to make a prior declaration** when they first intend to provide temporary services in another country, and every year thereafter if the host Member State requests it. This declaration provides competent authorities with important information concerning which healthcare professionals are providing services in their territories. This is relevant for patient safety, but also for workforce monitoring and planning.

2.3. Principle of partial access – Article 1(5)

EPF welcomes the clear wording in the proposal that explicitly excludes healthcare professions from the scope of the principle of partial access,⁹ and we urge the European Parliament and the Council to maintain this wording.

⁸ The Commission proposal is that patient organisations should have the right to request language testing for all self-employed professionals only, testing to be done by a clearly identified body within the national healthcare system

To protect patients' safety and quality of care, **the principle of partial access must not apply to healthcare professions**. Partial access would result in an unacceptable downgrading of educational requirements and would undermine the ongoing initiatives to improve the quality and safety of care across the European Union. It would also create confusion for users of healthcare services.

2.4. Temporary provision of services

EPF's main concern regarding temporary provision of services is that the distinction between this and longer-term establishment is not clearly drawn either by the draft Directive or by the European Court of Justice's case-law. The checking of qualifications of healthcare professionals is different under the two regimes ; this has implications for patient safety.

From a patients' perspective, **having lower requirements for temporary mobility is not justified under any circumstances** – the priority should be to ensure safety and quality of care. Furthermore, EPF believes that an **annual declaration should continue to be required from all healthcare professionals**, including those with an EPC. The Directive should make it compulsory on Member States to request evidence that a health professional is qualified and fit to practice before they start providing services, and at each annual declaration.

The proposal obliges Member States to draw up a list of “professions with health and safety implications” that may be subject to a prior check of qualifications, and clarifies the list of documents Member states may require before a first provision of services. **The patients' perspective should be considered when defining what “health and safety implications” means for different categories of health professionals.**

2.5. The general system for the recognition of qualifications

The general system applies to those healthcare professions who do not fall under automatic recognition (“allied health-related professions”). The general system is based on five levels, determined according to an individual's diplomas or professional experience. Currently, an individual whose qualification is two levels below the one for the profession s/he wishes to practice (in the receiving Member State) is automatically rejected.

The Commission proposes that competent authorities should judge on a case-by-case basis, keeping the five levels as an indication only. While flexibility would be a positive thing to facilitate professional mobility, EPF is concerned of the potential implications for the safety of patients. **Competent authorities should be explicitly required to take into account these implications** when taking a decision related to application of healthcare professionals.

2.6. Improved transparency on national qualifications and diplomas – Article 1 (16)

EPF welcomes the obligation on Member States to report to the Commission and early notification of new education programmes and diplomas. It is important to ensure that national education and training programmes comply with the Directive. This provides a basis

⁹ the principle of partial access means that professionals who are qualified to exercise their profession in the home Member State could have access to parts of a similar profession in another Member State.

to ensure that healthcare professionals' qualifications comply with minimum requirements for safe and high-quality care.

2.7. List of competences and skills for healthcare professionals – Article 1(18), 1(22), 1(24), 1(27), 1(28)

EPF believes that health professionals' education and training should be measured in terms of competencies and outcomes, rather than length of training. **Patients can play a valuable role in identifying training needs for the health workforce from a service user's perspective.** Cooperation with patients' organisations in developing competences for health professionals and updating medical education should be strongly encouraged. When drafting the delegated acts, the Commission should involve all relevant stakeholders, including patient organisations.

The patient's role has changed enormously since Directive 36 was first implemented – patients have moved from passive recipients of care to empowered, health-literate actors who participate actively in their healthcare. The Council recognises “*patient-centeredness*” as a common operating principle of European health systems.¹⁰ Appropriate training of healthcare professionals is key to realising patient-centred healthcare in practice, including shared decision-making and a partnership approach to chronic disease management. This is vital for the future sustainability of European health systems, where guided self-care, eHealth and remote monitoring, and personalised healthcare are likely to play a major role.

Example: **communication skills.** Patients' ability to understand medical issues, health and lifestyle advice is closely linked to the clarity of the communication of health professionals: studies suggest that patients do not receive enough information, and that health professionals overestimate the amount and quality of the information they supply. Patients need and want health professionals to communicate effectively with them regarding diagnosis, treatment options, risks, benefits, implications for quality of life, etc. This will empower them to understand their condition, ask the right questions and make informed decisions concerning their health. It will also make the best use of health professionals' time, and lead to better quality healthcare from both viewpoints.

Specialist nurses play a key role in many disease areas as care coordinators and patient advocates. Diabetes nurses are well known, but other successful initiatives exist, for example in Parkinson's disease, Multiple Sclerosis, and breast cancer.¹¹ EPF recommends that specialist nurse programmes should be comprehensively mapped, evaluated, and shared across Europe.

¹⁰ Council Conclusions on Common values and principles in European Union Health Systems, 2006, available [here](#)

¹¹ On breast cancer nurses (BCN) see the European Guidelines for Quality Assurance in Breast Screening and Diagnosis (4th edition, European Commission, published 2007) [here](#), Some European countries (the UK, Netherlands) have specialised BCN training at their universities and a few (Germany, Switzerland) have “non-academic” training; the European Oncology Nursing Society (EONS) published its post-basic curriculum for breast care nursing see http://www.cancernurse.eu/education/post_basic_curriculum_in_cancer_nursing.html

2.8. Partial exemption – Article 1(19)

In order to enhance the mobility of doctors who have already obtained a specialist qualification and afterwards wish to follow training in another specialism, the Commission's proposal would allow Member States to grant partial exemptions from some elements of the training in certain cases detailed in the proposal.

EPF is supportive of this provision. We believe that partial exemptions can be **an incentive to encourage specialisation**, because a doctor would not more willing to invest in further training they did not have to repeat those parts that were already covered by their earlier training. Furthermore, doctors' interest in acquiring high expertise in a specialised area can be encouraged if this competence will also be recognised in another field. For example, expertise in rare diseases requires multidisciplinary competences, which can only be acquired through different specialties.

Conclusion

Modernising the EU regulatory framework for professional qualifications is essential to achieving an EU health workforce with the right skills and competences to face the shared European challenges related to the quality and sustainability of our health systems. Integrating the patients' perspective in this review is the key to achieve a framework that centres around the patients' needs and their right to receive safe, high quality healthcare everywhere in Europe.

The European Patients' Forum welcomes the Commission's proposal for a review of Directive 36 which is in our view a step forward as it identifies patient safety as a key objective. This paper has outlined the areas where EPF believes the proposal needs to be improved. EPF and our members are committed to being proactive partners with the EU Institutions and stakeholder organisations in the legislative process, to ensure that the revised Directive reflects patients' needs and contributes to high standards of safety and quality, as well as accessible care, for all patients across the EU.



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