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ЕВРОПЕЙСКА АСОЦИАЦИЯ НА СТАРШИТЕ БОЛНИЧНИ ЛЕКАРИ
ASOCIATIA EUROPEANA A MEDICILOR DIN SPITALE

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Updates of EU policy on, or with an impact on, health
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Policy Officer

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1. Adoption of the revision of the European Directive on automatic recognition of professional qualifications (36/2005/EC)

Adopted by the European Parliament (EP) on 9 October and the Council (Member States) on 15 November.

The 2005 Professional Qualifications Directive that is just being implemented, already needed to be revised to put a strong emphasis on the use of modern technologies and to cut through red tape and speed up procedures (the use of the Internal Market Information System (IMI) for the European professional card will simplify recognition procedures for applicants and for competent authorities for instance).

Differences between the 2005 and the 2013 Directive – main elements:

1. The introduction of a European professional card: easier and quicker recognition of professional qualifications and to facilitate temporary mobility. The card will be made available according to the needs expressed by the professions. The card is linked to an optimised recognition procedure carried out within the existing Internal Market Information System (IMI) and will take the form of an electronic certificate, allowing the professional to provide services or become established in another Member State.

2. Better access to information and access to e-government services: Member States will make available all information about recognition of qualifications (in particular, a list of competent authorities and of documents required) through the *Points of Single Contact* which were created under the Services Directive and are already in operation. *Professionals will also have the possibility to complete recognition procedures online*. In addition, the existing *national contact points will become assistance centres, responsible for providing advice and assistance on individual cases*.

3. Modernisation of harmonised minimum training requirements: the revised Directive introduces changes in the definition of the minimum training requirements for the professions benefiting from automatic recognition (doctors, nurses, midwives, dentists, pharmacists, veterinary surgeons and architects).

   For doctors, the revised Directive clarifies that *basic medical education should be based on 5,500 training hours, which can be done within a minimum of five years*. In addition, the revised Directive introduces the possibility for Member States to give *partial exemptions to specialist doctors willing to follow a second specialist training and introduces a specific acquired rights regime for certain doctors qualified in Italy*.
   For nurses, the revised Directive foresees the introduction of a common list of competences which would complement the already existing knowledge and skills and training subjects for the studies. For dentists, the amended Directive updates the minimum training requirement in order to specify that it has to consist of 5,000 training hours.

For midwives, the revised Directive upgrades the entry level to midwifery training from 10 years to 12 years of general education for those midwives who start their professional training directly after finishing their general education. That said, the amended Directive does not require Member States to introduce university training for midwives and would also allow Member States to provide for solutions equivalent to the 12 school years.
For pharmacists, the amended Directive updates the list of activities of pharmacists in line with the latest developments of this profession and restricts the application of the exception allowing Member States to refuse the recognition of the professional qualifications for the opening of new pharmacies.

4. An alert mechanism is set up for all professions with patient safety implications and professions involved in the education of minors, including childcare and early childhood education (where the profession is regulated). The revised Directive effectively introduces an *obligation for competent authorities of a Member State to inform the competent authorities of all other Member States about a professional who has been prohibited, even temporarily, from exercising his professional activity or who made use of falsified documents*. This exchange of information will be based on the use of the Internal Market Information system (IMI).

5. Common training principles: the modernised directive introduces the *possibility to set up "common training frameworks" and "common training tests", aimed at offering a new avenue for automatic recognition*. A common training framework should be based on a *common set of knowledge, skills and competences necessary to pursue a profession.* A common training framework or test could be set up if the profession concerned or the education and training leading to the profession is regulated in at least one third of the Member States. Qualifications obtained under such common training frameworks should automatically be recognised in the other participating Member States. Specialties of sectoral professions may also develop common training principles. The Commission may introduce such frameworks by delegated acts. Member States may be exempted from the application of common training frameworks or tests under specific conditions.

6. Mutual evaluation exercise on regulated professions: a new mechanism is introduced in the Directive to ensure greater transparency and justification of regulated professions. *Member States will have to provide a list of their regulated professions and the activities reserved for them, and justify the need for regulation*. This should be followed up by a mutual evaluation exercise facilitated by the European Commission. In a Communication of 2 October 2013, the Commission presented a work plan for carrying out the mapping and mutual evaluation of regulated professions.

7. Rules on partial access to a regulated profession: the principle of partial access – access to part of the activities reserved to a particular profession - is included in the new directive. It can benefit professionals who engage in a genuine economic activity in their home Member State which does not exist, in its own right, in the Member State to which they wish to move.

8. Extending the scope of the Directive to professionals who are not fully qualified: professionals who hold a diploma but have yet to complete a professional traineeship before getting full access to the profession will be able to benefit from the Directive which clarifies the relation of the professional with the home Member State where the professional has been previously trained. This professional traineeship is required under the law of some Member States, for example for lawyers, architects and teachers. However, Member States may limit the duration of the part of the professional traineeship which can be carried out abroad. They will have to publish guidelines on the organisation and the recognition of professional traineeships carried out abroad.

9. Improving temporary mobility: the amended Directive reduces the professional experience requirement for professionals coming from non-regulating Member States and clarifies document requirements and the procedural steps.

10. Rules on language skills: the revised Directive clarifies that the *checking of the language knowledge of a professional should take place only after the host Member State has recognised the qualification but it might intervene before the professional accesses the profession*. *In the case of professions with implications for patient safety, competent authorities may carry out systematic language controls*. In other cases, language control can intervene only if the competent authority has a serious and concrete doubt regarding the language knowledge of the professional. In any case, language control should be limited to the knowledge of one official or administrative language of the host Member State.

11. Continuous professional development: according to the new Directive, Member States will have to ensure that sectoral professions (doctors, nurses, midwives, dentists, pharmacists, veterinary surgeons and architects) can update their knowledge, skills and competences via continuous professional development. The Commission recently launched a study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU (of which CPME is a leading partner).

The Directive foresees a two-year transposition period for the Member States. To date more than 265,000 citizens have taken advantage of the EU rules in seeking recognition of their professional qualifications since 1998 when Member States began collecting statistics. The actual number is estimated to be much higher as notified statistics have been incomplete and in any event did not cover professionals moving just on a temporary basis.

2. Implementation of the Cross-border and patients mobility Directive

Under the new Directive, EU citizens who choose to obtain a health service (including private and unplanned care) in another Member State can seek reimbursement of the costs they will have paid up front, provided that the service is the same as or equivalent to a service that would have been provided to the patient at home. The right to claim a reimbursement is limited to the cost to his/her national social security of the same or equivalent treatment or the actual amount paid by the patient, where this is less. In some instances, the patient seeking a treatment abroad will have to first ask for a prior authorization from his/her national authority – but this shall be the exception, not the rule. Patients will have to pay for the care upfront and ask for a reimbursement when back at home but Member States have the option of paying for the healthcare directly, rather than reimbursing patients. The Directive also puts in place a system of recognition of prescriptions and networks on Health Technology Assessment (HTA)

Since the 25th of October, the Directive on cross-border healthcare is to be fully implemented by every EU Member States. However, it appears that some are yet to make it reality. These will be subjected to European Commission sanctions for not respecting the deadline for implementation.

What the Directive means for Member States, firstly, they should all have a National Contact Point which serves as a source of information and a coordinator in certain instances. To this date, 8 countries are still to communicate their NCP (including France – whole list is available here: http://ec.europa.eu/health/cross_border_care/docs/cbhc_ncp_en.pdf). They should all have a system in place to:

- manage claims for reimbursement of treatment costs;
- manage applications from patients seeking prior authorisation for the receipt of healthcare in another EU state; and

- support healthcare providers who may receive requests from overseas patients for treatment in the HC provider country under the provisions of the directive.

3. Health workforce initiative: EU Joint Action on Health Workforce Planning

The general objective of this action is a platform for collaboration and exchange between MSs to prepare the future of the HWF. This will support MSs and Europe in their capacity to take effective and sustainable measures. Colleagues from CPME, UEMS, CED, EHMA, EFN, HOPE and PGEU are partners in the Action Plan.

The Joint Action on Health Workforce has 3 Horizontal Work Packages and 4 Core Work Packages.

More information: http://euhwforce.weebly.com/

4. Working time Directive

There has been no progress on negotiations between the EU representatives and the social partners to find an agreement on this subject; the issues remain on the count and the way to count working hours (does 'on call' availability count as working hour, even if not spent at hospital?), the opt-out options, and the number of hours work per week.

5. Other health related topics on the present EU agenda – in italic: binding for EU Member states:

a) health inequalities,
b) need for health systems reforms,
c) a future plan to tackle chronic non-communicable diseases,
d) the revised *Tobacco Products Directive*, as part of Commission work on health determinants (including alcohol, physical activity and diet),
e) the *Medical Trials Regulation*: some physicians have expressed concern about weakening the "informed consent" which they believe, has been weakened in the piece of legislation, stating that "broad or simplified consent introduced in the regulation are not consistent with the concept of purpose limitation." "It is unclear how the privacy of the data subjects will be ensured, since there is no clear obligation in the text to anonymise or at least pseudonymise the data "(CPME)
f) the revised *Medical Devices Directive and in vitro diagnostics*, which involve increased pre and post -market procedures, to help protect patient's safety. The new regulations tighten up requirements so that manufacturers develop better designed devices that can reach the end of their expected life time without causing hazards for individuals – with pre–market authorisation process, special notified bodies designated by the European Medicines Agency, post-market monitoring and vigilance
g) the on-going European Innovation Partnership in Active and Healthy Ageing
h) the Safety and Health at work strategy – ended in 2012 and is not renewed, it continues as such,
i) development of health technology and eHealth, in particular: there are two eHealth related ongoing projects Renewing Health and Momentum are of interest to doctors, and the European Commission launched this year a consultation on mHealth
j) *EU Decision on cross-border health threats*,
k) *pharmacovigilance*: new inverted black triangle on medicine packs & product information: medicines under additional monitoring and to encourage reporting of suspected adverse reactions,
l) Regulation of data protection