

Position Paper of the European Association of Health Competent Authorities (EurHeCA)

On the proposal for a directive amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation on administrative cooperation through the Internal Market Information System COM(2011)883

EurHeCA, an association born in 2011, consists of Member-states' health competent authorities (for doctors, pharmacists, nurses, midwives, dentists)¹. EurHeCA members believe in the need to promote the free movement of health professionals within the European Union. Therefore, they welcome the revision of the directive on the recognition of professional qualifications proposed by the European Commission. After a close review, EurHeCA considers that this proposal makes substantial improvements. However, EurHeCA also calls for certain reservations and clarifications with regards to the protection of patients and recognition of professionals through a European "card".

1. RESERVATIONS RELATING TO THE PROTECTION OF PATIENTS

One of the chief missions of health competent authorities is to ensure the protection of patients and access to quality healthcare. In this respect, EurHeCA shares the concerns that have been expressed for several months by numerous professional organisations regarding partial access, control of language skills and alert mechanisms.

1.1. Partial Access

The concept of partial access shall not be set as a general principle and extended to health professions, in view of risks to the patient interacting with a health professional whose level of competence would not be completely ensured. The possibility to refuse partial access for public health reasons is certainly set in the directive but it does not seem advisable to have this kind of decisions taken on a case-by-case basis.

→ EurHeCA requests that all health professions be excluded from the scope of partial access.

1.2. Control of language skills

In the field of health, the control of language skills is not only a legal issue, but also an ethical one. For health professions, the assertion of language domain is one of the prerogatives applied that prevents errors, so costly in health, and is one of the tools to protect the patient from gross mistakes.

That is why **EurHeCA** believes that, in order to protect patients, the control of language should be mandatory, carried out before the granting of the final authorization to practice and EurHeCA believes this mandatory control must apply whatever the practice context is.

Competent authorities, as guarantors for the quality of the professional practice, shall be systematically and actively involved in this control. The issue of the funding of this control is still to be examined.

→ EurHeCA requests that the control of language skills be mandatory and carried out before the final authorisation to practice is granted, involving systematically the competent authority of the host country.

¹ Founding Members: Ministère de la Santé (BE), Ordre national des pharmaciens (BE), Bulgarian Pharmaceutical Union (BG), Consejo General de Colegios Oficiales de Enfermería (ES), Consejo General de Colegios Oficiales de Farmaceuticos España (ES), Conseil national de l'Ordre des pharmaciens (FR), Pharmaceutical Society of Ireland (IE), Malta Pharmacy Council (MT), Naczelna Izba Aptekarska (PL), Ordem dos Farmaceuticos (PT), Colegiul Medicilor din România (RO).

1.3.Alert mechanism

EurHeCA welcomes the establishment of a mechanism for the competent authorities of all Member States to be alerted in case a professional is prohibited to practice. However, to respect the principle of presumption of innocence, it is imperative that alerts only refer to final decisions, as mentioned by the European Data Protection Supervisor. Besides, the envisaged arrangements bring up a number of practical issues: how will information be circulated when the professional is abroad? Will the alerts be disseminated through IMI? The Commission shall specify who circulates information, how, and to what kind of recipient, whether the sanction was imposed in the home or host Member State.

→ EurHeCA emphasizes that the alert mechanism shall only refer to final decisions. It is also important that the procedure for disseminating information is specified.

1.4.Review timelines

The proposal provides, through the procedure of recognition of qualifications thanks to the European card, a substantial reduction in time required to review records by the competent authorities.

→ The competent authorities Members of EurHeCA consider that it is necessary to provide a realistic deadline for the competent authorities of the host Member State to carry out the recognition procedure. In addition, members of EurHeCA propose to delete the concept of non-suspensive delay in case the competent authority requires additional information, and the "tacit validation" for failure to answer the competent authority of the host country on time. Indeed, this could lead to situations where recognition would be granted unless the competent authorities have been able to make the necessary checks to ensure the competence of professionals and patient protection.

1. COMMENTS AND REQUESTS FOR CLARIFICATION REGARDING THE EUROPEAN PROFESSIONAL CARD

Collaboration between today's members of EurHeCA began with the European HPRO Card project (2007-2009).² This project produced an inventory of European health competent authorities, of tools for identifying professionals, of prerequisites for authenticating professionals and interoperability of the various identification systems. Being particularly sensitive to the European professional card project, EurHeCA wishes to lend its expertise to the Commission. Indeed, while EurHeCA members support the introduction of this tool, they are concerned about some technical and procedural issues.

1.1.Format of the European professional card

The proposal is not clear enough about the format envisaged for the European professional card. The names "card" and "electronic certificate" which are used alternatively apparently refer to a mere "certification document put on line". Yet "electronic certificate" and "certification document put online" are anything but synonymous. An "electronic certificate" is an electronic seal providing a proof of identity, signed electronically by a certifying authority and using security algorithms. This type of tool is part of most existing chip cards. On the other hand, a "certification document put online" is just a shared file.

Documents put online, as much as chipless plastic cards, are really insufficiently secured tools that tend to become obsolete; on the other hand, electronic certificates are a modern and flexible tool, that can be embedded on any appropriate device (professional or identity chipcard, smartphone, etc.), left to the discretion of Member States. The chosen format also impacts the European professional card's validation deadlines: the suggested deadlines are too short if competent authorities need to inspect and check certification documents put online, while they are perfectly suited if competent authorities can check instantaneously an electronic certificate against information contained in databases.

→ EurHeCA requests that the directive define the card as an "electronic certificate" in the sense referred to above.

² Funded by the Directorate General for Employment, Social Affairs and Inclusion, European Commission.

1.2. Required data for the issue and use of the European professional card

The directive does not specify yet which data a professional wishing to move in another Member State will have to provide for the card to be issued. In view of increasing interaction between competent authorities and in order to issue the European card, it would be advisable to agree on a common minimum set of information contained in the databases of each competent authority.

→ *EurHeCA suggests to work towards convergence of items to be exchanged by databases.*

1.3. Connection with IMI and procedural issues

The circuit that is to be used to circulate information between the home and host States needs to be clarified. The respective roles of competent authorities, professionals, IMI and IT tools in the process should be specified.

The draft directive does not state how electronic certificates are connected to IMI. EurHeCA does not want IMI to become a European database. All current European IT projects (epSOS, STORK, EESSI³, etc.) have chosen to encourage exchanges between Member States rather than centralising information at European level. There are technical, legal and organisational reasons for this. IMI should be the portal to access existing databases for competent authorities as well as for patients and employers (with differentiated access and in compliance with European legislation on the protection of personal data).

→ *EurHeCA suggests a system architecture based on exchanges between competent authorities through IMI, without creating a European database.*

The validity period of for the card (two years) is not justified and would create legal uncertainty by blurring the boundaries between the free provision of services and establishment.

→ *EurHeCA considers that the card should have the same validity period than the declaration of free provision of services, so one year (and not two).*

Various procedural issues

A number of practical questions need to be answered. EurHeCA wishes to raise them in order to help the European Commission in improving the efficiency of the procedure and adding real value to the European professional card.

Card validation

- *How does the home competent authority inform the host competent authorities of the creation of the card?*
- *Does it go through IMI?*
- *How do we know which competent authority is to be informed? (Currently there is some vagueness in this matter in some Member States.)*

Issue of the card

- *Is the card (irrespective of its format) issued to the professional at the end of the procedure?*
- *If the chosen card format is an electronic certificate, could it be embedded on a national (professional) chipcard?*
- *In this case, how does the home competent authority receive the national (professional) card?*
- *How does the professional work without the card during the loading of the certificate by the competent authority?*

³ epSOS: Smart Open Services for European Patients, STORK: Secure idenTity acrOss boRders linKed, EESSI: Electronic Exchange of Social Security Information.

- *If a professional has had a card validated for establishment in a foreign Member State⁴ and wishes to practice in another Member State, what is the procedure?*

1.4. Subsequent functionalities of the European professional card

If the European professional card is an electronic certificate, it would have even more added value by integrating further functionalities in the future: telemedicine, continued professional development monitoring, e-prescription, access to health records.

→ Overall, EurHeCA requests that competent authorities be associated in the delegated acts' preparatory work and/or pilot projects that will further specify the procedures to be used for recognition through the European professional card.

⁴ Cf. articles 3 and 4quater.