Pharmaceutical Society of Northern Ireland

CONSULTATION PAPER BY DG INTERNAL MARKET AND SERVICES ON THE PROFESSIONAL QUALIFICATIONS DIRECTIVE

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The Pharmaceutical Society of Northern Ireland (PSNI) is the regulatory and professional body for pharmacists in Northern Ireland.

It protects public safety in pharmacy by:
- setting and promoting standards for pharmacists' admission to the register and for remaining on the register;
- maintaining a publicly accessible register of pharmacists, and pharmacy premises;
- handling concerns about the Fitness to Practise of registrants, acting as a complaints portal and taking action to protect the public; and
- Ensuring high standards of education and training for pharmacists in Northern Ireland.

As the professional body it seeks to develop the pharmacy profession in Northern Ireland in the public interest. In future, this role will be conducted by a Professional Forum.

The PSNI has reviewed the DG INT consultation paper of 7 January 2011 and makes the following principal responses to the questions posed below:

Question 1: Do you have any suggestions for further improving citizen's access to information on the recognition processes for their professional qualification in another Member State?

A centralised website signposting the competent authorities (CAs) in each Member State responsible for the regulation of each profession would be useful.

Through this single portal all competent authorities could be accessed and should present information in a standardised manner.

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

All Member States (MS) should commit to using a single standardised process for applications. This would offer harmonisation across CAs and speed applications as all processes would be uniform.

However, in conducting any exercise in process standardisation, scope for checking the authenticity of supplied documentation must be maintained.
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.

No, it should be a voluntary code not a mandatory one. Any move to a mandatory code would raise questions as to who would enforce such a code and how organisations would be made accountable.

Otherwise, the Code of Conduct is laudable in its intent and provides useful guidance.

Question 5: Do you support the idea of developing Europe-wide codes of conduct on aptitude tests or adaptation periods?

While this makes sense if it was harmonised there remain substantial barriers to the integration of all professions to a standard code. The resulting standard may be so general as not to have any particular value. This would require substantive audit to ensure the consistency and quality assurance of decisions by CAs.

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.

This has some possibilities but it would need clearer definitions as to qualifications and greater harmonisation of qualifications across CAs there would need to be research to evidence any potential benefit to citizens.

There could be standardised defined programmes of activity which would be available to graduates across Europe and completion of this programme will give the proof to the host CA that the training had been successfully completed.

Difficulties will arise with the differences between the healthcare systems of each member state and the variations between private and state sponsored healthcare. There will also be difficulty in at what time and level the supervised practise is obtained.

Question 8: How should the home Member State proceed in case the professional wishes to return after a supervised practice in another Member State? Please be specific in your reasons.

Again this is a matter for each home state in that there would need to be extensive evaluation of any experience received in the state visited and relate this to the requirements of the host state. Again when in the process the experience is gained is an important consideration. It is difficult to see this integrated into the varied qualifications offered in pharmacy in member states.

This is not a simple process and may be subject to costs and delay of registration if not harmonised properly. The Commission could give CAs flexibility in this matter.
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?

PSNI recognise the concept of a European Professional Card has possibilities in relation to using the IMI system for fast track registration of persons with acquired rights, and offering potential simplification to the registration process.

However, any system of a European Professional Card would need to overcome important challenges in relation to:

1. preventing forgery;
2. containing cost;
3. remaining accurate and contemporaneous; and,
4. ensuring data protection of the individual whilst at the same time providing CAs with relevant details of health and fitness to practise history.

In short, any system of a professional card, that was: liable to forgery; increased the cost of professional regulation; provided unreliable information about individuals to CAs and employers; breached individuals’ data protection rights; and, failed to address the ongoing difficulties in relation to sharing Fitness to Practise information across countries, could greatly damage confidence in the systems of recognition for professional qualifications.

It is therefore essential the 4 challenges above are robustly met in the context of any further development of Professional Card proposals.

Question 12: Do you agree with the proposed features of the card?

From the perspective of a regulatory body, whose principal duty is to protect patient safety, an essential feature of any such card is the inclusion of access to information on the individual’s Fitness to Practise history, and accurate information about the individual’s level of qualification.

In relation to the health professions, the protection of patient safety should be a core objective of the card.

Question 13: What information would be essential on the card? How could a timely update of such information be organised?

Real time access to the host CA via an encrypted password which is embedded on the card plus an additional PIN.

Access to an individual’s Fitness to Practise history and accurate information on their level of qualification would be essential information.

The contemporaneous nature of the information on the card is essential to CA, employer and public confidence in such a system.
**Question 14:** Do you think that the title professional card is appropriate? Would the title professional passport, with its connotation of mobility, be more appropriate?

Professional passport is generally a desirable title as it suggests portability. However, the term “Professional Passport” would really only be appropriate if the system met similar standards to national passports in terms of robust anti-forgery measures, and real time access for the CA to the individual’s qualification, registration and Fitness to Practise history.

**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?

*Prior Declarations*
There is scope for formalising the prior declaration regime to give both applicant and CAs greater certainty about the process.

*Temporary and Occasional*
There would be great value to both the regulator and individual of having the terms “temporary and occasional” better defined.

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

Yes, particularly in the health professions in order to protect the public from professionals with Fitness to Practise issues. Accordingly, it may be that patient facing professions merit separate treatment under the terms of a revised Directive.

**Question 20:** Should Member States reduce the current scope for prior checks of qualifications and accordingly the scope for derogating from the declaration regime?

No, because evidence suggests that all member states do not operate the same levels of checking prior to registration.

The need to simplify the registration process for professionals crossing borders must be balanced against the needs of protecting patient safety, especially in patient-facing professions. Accordingly, it may be that patient facing professions merit separate treatment under the terms of a revised Directive.

**Question 21:** Does the current minimum training harmonisation offer a real access to the profession, in particular for nurses, midwives and pharmacists?

Automatic recognition of pharmacists should continue to be based on the diploma and Annex V that currently forms part of the Directive. Our experience has shown that it continues to be necessary for the various diplomas, documentation, professional standing, etc of applicants to be checked prior to recognition. This is particularly important where patient and public safety considerations are at issue and where in a notification system, the facility for intervention may arise too late and after considerable damage to patients or the public may have arisen.
**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?

Yes. In relation to pharmacy, particularly in the UK, there is a move in the role from the supply of medicines to more clinical aspects of practise.

The knowledge and skills in the Directive represent part of the scientific basis of the discipline but do not adequately reflect the current state of pharmacy as a clinical healthcare profession in the UK. In summary, we argue that the full basis of the discipline would be:

- Practise safely & effectively
- Practise ethically and lawfully
- Understand and apply biomedical and pharmaceutical science principles, method and knowledge (covered in the Directive)
- Understand and apply psychological and social principles, method and knowledge
- Understand and apply population and improvement science principles, method and knowledge

**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?

Yes. In the rapidly advancing health sector, CPD is an important part of ensuring an individual’s professional knowledge is kept up to date. There can be patient safety implications from failing to do so. CPD is now mandatory for nearly all health professions in the UK.

**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?

Yes.

There is scope for more efficient cooperation between competent authorities across the EU, and the Commission should explore any role it may have, whether through a review of the Professional Qualifications Directive or otherwise, in bringing such improved cooperation about.

It is the view of the PSNI that IMI has been a proven and useful tool in aiding cooperation between CAs and represents a good platform of success to build upon.

While alerts can be initiated there must also be a mechanism to stand them down and circulate this too.

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

High risk practitioners who move to other states and bring the risk with them.

An alert obligation upon MS CAs could be a useful mechanism for reinforcing
confidence in labour mobility across the Union, especially amongst the health professions. For its operation however, current obstacles in sharing Fitness to Practise information across borders should be addressed. Obstacles in particular are the interpretation of domestic data protection legislation in some states that prevents such exchange of information from taking place. The Commission might use its position of legislative primacy to address this in the context of the review of the Professional Qualifications Directive.

Alerts should be triggered by:
- presentation of a fake diploma
- notification of a relevant criminal conviction
- notification of sanctions upon, or withdrawal of, an individual’s licence to practise

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

The current language regime places health professional regulators in a difficult position. The RB’s statutory role is to protect the public by means of maintaining a register of Fit to Practise professionals. However the Directive prevents denial of registration to an EU professional with no language competency in the host state’s principal language. The public, and other stakeholders, find it difficult to reconcile this with their expectation of a regulatory body’s role.

The PSNI urge the Commission to consider, against the needs of patient safety, what powers can be given to RBs to conduct reasonable levels of language testing of applicants to the register, in order to provide the levels of assurance expected by the public. Further clarity from the Commission is still required in relation to this matter.

**Further information**

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