Response to the Department for Education and Skills consultation on The European Communities (Recognition of Professional Qualifications) Regulations 2007.

Introduction

The Royal Pharmaceutical Society of Great Britain (RPSGB) is the professional and regulatory body for pharmacists in England, Scotland and Wales. It also regulates pharmacy technicians on a voluntary basis, a role that is expected to become statutory under new legislation soon. The primary objectives of the RPSGB are to lead, regulate, develop and represent the profession of pharmacy.

The Society is supportive of the Directive as a whole but welcomes this opportunity to re-iterate its grave concerns relating to temporary service provision and to the way the provisions have been interpreted for the purposes of transposition into UK law. The Society is concerned that in this one area the proposed regime is not consistent with the focus on patient safety that we all agree must be at the heart of professional regulation.

Patients and the public have a right to expect the same standards and level of protection regardless of whether the healthcare professional treating them is established in Great Britain or providing services temporarily.

In relation to the temporary provision of services and the introduction of a 'visiting EEA practitioner' category the Directive must be applied in a way that enables the Society to regulate efficiently and effectively.

The Society strongly believes that the interpretation and implementation of Directive 2005/36 conflicts with the statements contained in recitals 3 and 44 of the Directive itself.

Recital 3 states
'The guarantee conferred by this Directive on persons having acquired their professional qualifications in a member State to have access to the same profession and pursue it in another Member State with the same rights as nationals is without prejudice to compliance by the migrant professional with any non-discriminatory conditions of pursuit which might be laid down by the latter member State, provided that these are objectively justified and proportionate'

Recital 44 states
'This Directive is without prejudice to measures necessary to ensure a high level of health and consumer protection'.

The Society also strongly believes that the implementation of this Directive conflicts with the Society's general duties as specified in 4(1)(a)(i) and (ii) of the Pharmacists and Pharmacy Technicians Order 2007, namely to have proper regard to the interests of persons using or needing the services of registered pharmacists or registered pharmacy technicians in Great Britain'.

The Society's concerns include:

1. The absence of any requirement for 'visiting EEA practitioners' to Britain to comply with the Society's Continuing Professional Development (CPD) requirements which would apply to all those who are on the practising register.
   The Society requests that the Department share with the Society and other healthcare regulators the legal basis for their view that temporary service providers cannot be required to undergo CPD, or provide evidence of CPD undergone in their Member State of establishment if relevant.

   It is difficult to see the justification in public protection terms for exempting temporary service providers from the requirements regarding CPD and revalidation that practising health professionals will be required to meet under UK legislation.

   It is a requirement in our Code of Ethics that all practising pharmacists and technicians must undertake CPD. This will become a statutory requirement when the Education and CPD rules come into force under the Pharmacists and Pharmacy Technicians Order. Clarification is needed on whether somebody on part 3 of the Register is exempt from all, part of or any of the Code of Ethics

2. The entitlement to practise as a 'visiting EEA practitioner' being based on the individual being 'legally established' in a member State without a clear definition of what is meant by lawful establishment.

3. A limitation on information which can be exchanged between the Society and the Competent Authority in the Member State of establishment, regarding practitioners wishing to provide services in Britain. The Directive limits this exchange to information concerning the legality of the service provider's establishment in a Member State, his good conduct and 'disciplinary *matters or criminal sanctions of a professional nature'.*

   Legislation must permit the Society to seek information from the Member State of establishment concerning other criminal sanctions and matters relating to poor performance or health of the service provider.

   The Society is also concerned that the regulation of pharmacy is not consistent throughout Europe and that the service provider's Member State of establishment may well not have as robust fitness to practice procedures as in this country.

   The Society's response to the consultation questions follow.

(i) Do you agree that competent authorities should act as the contact point for their profession?

Yes
The RPSGB and the PSNI have been designated as the Competent Authorities for pharmacists.

The profession of Pharmacy Technician is to be included in Schedule 1 Part 1 when registration of pharmacy technicians becomes statutory in England, Scotland and Wales.

The RPSGB has worked co-operatively with other Competent Authorities across Europe and continues to be an active participant in Europe-wide projects and initiatives such as the Health Professions Crossing Borders project and the Internal Market Information System. These projects aim to improve procedures for reactive and pro-active information sharing between Competent Authorities on fitness to practise issues and matters relating to qualifications.

Under the Directive the contact point is also to provide the migrant with information about the profession, its professional rules and code of ethics. The Society is therefore best placed to act as the GB contact point for pharmacy in the interests of accuracy of information and the accessibility of such information.

(ii) Do you agree that service providers should be required to submit a written Declaration in advance of provision of services?

Yes

The Society will require all 'visiting EEA pharmacists' and, once statutory regulation of technicians is implemented, 'visiting EEA pharmacy technicians' wishing to provide pharmacy services in Great Britain on a temporary and occasional basis to submit a written declaration in advance of the first provision of services. It is imperative that the Society knows whether (in any given year) an individual may be practising in Great Britain.

The Society has been informed that the EU Commission is proposing a standard format for the written declaration. According to the EU Commissions' interpretation of these provisions, regulators will not be able to require applicants to provide, prospectively, details of the services to be provided nor the period(s) when they are to be provided in the declaration.

In the Society's opinion the Directive does not explicitly prevent regulators from requesting this information from applicants in advance of service provision. It seems rather odd that for presumably financial expediency, details of the service should be provided in advance to a public social security body but that advance notification to a regulator in the interests of public and patient safety should be prohibited.

Article 7 states

' Member States may require that, where the service provider first moves from one member State to another in order to provide services, he shall inform the competent authority in the host Member State in a written declaration to be made in advance <u>including</u> the details of any insurance cover ……'

The declaration therefore must include details of professional indemnity insurance but could additionally include information such as the nature of the service and where and when these are to be provided. Furthermore it will be impossible to assess whether the insurance cover is appropriate in the absence of any information on the intended nature of service provision or where and when the visiting practitioner intends to work.

Neither the Directive nor the draft regulations define what is meant by 'temporary and occasional'. At regulation 9 of the draft legislation it states that the 'Competent Authority shall assess on a case by case basis whether the provision of professional

services is on a temporary and occasional basis in particular in relation to its duration, its frequency, its regularity and its continuity'.

The Society therefore has to make a judgement but is concerned that the proposed legislation makes it impossible for that judgement to be made because in the written declaration we cannot require the applicant to tell us in advance about the nature or duration of the services he is intending to provide.

The legislation provides for an annual renewal of the declaration which means that it is clearly envisaged that a practitioner could benefit from these provisions over a number of years. The Society would have no means of knowing or basis for preventing a visiting EEA practitioner from practising regularly or continuously. The Society believes that a declaration should be provided in advance of each and every period of service provision. Furthermore the declaration is to be supported with certain documents on the first provision of services or *'if there is a material change in the situation substantiated by the documents'* (Regulation 12(1)(b)). How is the Society to know if there has been a 'material change'? In the interests of public and patient safety documents confirming a temporary service provider's fitness to practise should also be provided in advance of each and every period of service provision.

The DH regulations are to implement 'visiting EEA pharmacists' by amending the Pharmacists and Pharmacy Technicians Order 2007. In the Society's response to these regulations the Society has proposed an amendment to Article 33 (2) of the Pharmacists and Pharmacy Technicians Order to permit the Registrar to remove a 'visiting EEA practitioner' from the register if she receives no response to written enquiries regarding the nature of the services to be provided and where and when they are to be provided after 2 attempts.

(iii) Do you agree that service providers should be required to supply the UK competent authority with documentation accompanying the Declaration which provides proof of the service provider's nationality, legal establishment, professional qualifications and, for the security sector, evidence of no criminal convictions?

Yes
For the Society to comply with its regulatory function to act in the interests of public and patient safety it is important that the declaration is submitted with documents which provide

- evidence that the applicant is a national of a relevant European State, or
- if not a national of such a State, evidence of the Community right on which he intends to rely – i.e. evidence that they are to be treated as an 'exempt person' as defined in the Pharmacists and Pharmacy Technicians Order 2007.
- evidence of their qualifications and
- that they are legally established as a pharmacist in a Member State and not prohibited from practising (even temporarily) in that State.

Evidence that applicant is an 'exempt person'
If an applicant is not an exempt person then they are not covered by the Directive provisions. Evidence to support their rights to be treated as an 'exempt person' is therefore necessary.

Evidence of qualification
It is absolutely vital to ensure that a temporary service provider, in the interests of public and patient safety, is actually a qualified pharmacist and has met all the requirements for recognition. For example if an applicant holds a pharmaceutical sciences qualification from Member State A which would never permit pharmacy practice in that State, but subsequently obtains recognition (possibly erroneously) of this qualification and becomes legally established as a pharmacist in Member State B, then he should not be entitled to rely on establishment in Member State B to provide pharmacy services in another Member State.

In all cases therefore the Society would wish to confirm that the applicant does indeed possess a qualification which either entitles him to mutual automatic recognition or falls under the General System of recognition. The Society supports the provision in Regulation 14 which will enable the Society to assess an applicant's qualification against the national requirements for registration prior to the first provision of services in circumstances covered by Article 10 of the Directive.

It is absolutely vital to ensure that a temporary service provider, in the interests of public safety, is actually a qualified pharmacist and has met all the requirements for recognition.

Evidence that applicant is 'legally established'
The Society would wish to see a definition of 'legally established' in the legislation. This term appears to be crucial to the 'temporary service provider's' entitlement to provide services in Great Britain. Does the term 'legally established' mean that the applicant is required to have a permanent business base in his home Member State from which he intends to provide services? Or must the applicant have a contract of employment with evidence of continuity of employment before and after the period of temporary service provisions in Great Britain as evidence that he is indeed 'legally established in his home Member State for the purpose of pursuing the same profession there' ?

The Society does not believe that these provisions relating to the applicant being 'legally established' in a Member State are sufficiently robust to protect members of the public and patients. The Directive only requires the applicant to demonstrate that they are 'legally established' in a Member State for the practice of their profession. Persons wishing to avoid disciplinary proceedings may move from one jurisdiction to another, continuing to rely on 'legal establishment' in a Member State which is unaware of any past fitness to practise history.

The Directive and implementing legislation only requires the person to be legally established for the purpose of pursuing the same profession, it provides no safeguards in cases of dually qualified persons in circumstances for example where a practitioner who is dually registered as a doctor and pharmacist and who has been struck off as a doctor in his Member State of establishment nevertheless relies on establishment as a pharmacist to provide services in Britain.

It is important that the Society should be able to require 'visiting EEA practitioners' to provide details of all regulatory bodies with which they are or have been previously registered in their declaration prior to the first provision of services. This information is essential to enable the Society to check the applicant's fitness to practise with all relevant Competent Authorities.

The Directive imposes limits on information which can be exchanged between a host Member State competent authority and the Competent Authority in the Member State of establishment, regarding practitioners wishing to provide services here. The Directive limits this exchange to information concerning the legality of the service provider's establishment in a Member State, his good conduct and 'disciplinary matters or criminal sanctions of a professional nature'. This appears to exclude the ability of regulators to require information concerning other criminal sanctions and matters relating to poor performance or health of the service provider. Also it appears that a practitioner who has had conditions imposed on his registration in his home State as a result of fitness to practise action by the regulator, cannot be similarly restricted when providing services temporarily in Great Britain. If regulators are unable to apply equivalent practice restrictions to those in force in the practitioner's own home State, then patients here will be less well protected than has been thought necessary in the practitioner's State of origin.
There may even be a perverse incentive for a practitioner to provide services on a temporary basis in a jurisdiction where his practice is not limited in any way.

Similarly the Society would also wish to see a provision included in legislation clarifying that a pharmacist removed from the register by the Society's Disciplinary Committee or suspended from the register by the Disciplinary Committee or Health Committee could not rely on his 'legal establishment' in another Member State to provide or continue to provide pharmacy services in Great Britain on a 'temporary and occasional basis'.

Continuing Professional Development

The Directive in Article 5(3) states that
'Where a service provider moves he shall be subject to professional rules of a professional, statutory or administrative nature which are directly linked to professional qualifications, such as the definition of the profession, the use of titles and serious professional malpractice which is directly and specifically linked to consumer protection and safety, as well as disciplinary provisions which are applicable in the host Member State to professionals who pursue the same profession in that Member State'

The Society had envisaged that this would have permitted the Society to require 'visiting EEA practitioners' to comply with the Society's CPD requirements for practicing pharmacists.

The Society strongly disagrees with the view adopted by the DfES and acceded to by DH that requiring 'visiting EEA practitioners' to comply with CPD requirements 'would not be reasonable and proportionate'. Such a view is not acceptable and it does not sit well with the objective of ensuring the safety of patients and the public. It is envisaged by government that 'visiting EEA practitioners' will only have to fulfill the requirements imposed by their home regulators and there is an assumption that the home Member State has CPD requirements, in the absence of any assurance that other European countries are as advanced as the UK in their requirements for CPD and revalidation.

Regulation 9 states that all service providers will be subject to the professional rules and disciplinary provisions relevant to the profession. It is a requirement in our Code of Ethics that all practising pharmacists and pharmacy technicians must undertake CPD. This will become a statutory requirement when the Education and CPD rules come into force under the Pharmacists and Pharmacy Technicians Order.

Clarification is therefore needed on whether somebody on part 3 of the Register is exempt from all, part of or any of the Code of Ethics?

In the ECJ case of Sager C-76/90, it is stated that:

'Having regard to the particular characteristics of the provisions of services in certain sectors of activity, specific requirements imposed on the provider, which result from the application of rules governing those types of activities, cannot be regarded as incompatible with the Treaty. However, as a fundamental principle of the Treaty, the freedom to provide services may be limited only by provisions which are justified by imperative reasons relating to the public interest and which apply to all persons or undertakings pursuing an activity in the State of destination, in so far as that interest is not protected by the rules to which the person providing the services is subject in the Member State in which he is established. In particular, those requirements must be objectively necessary in order to ensure compliance with professional rules and to guarantee the protection of the recipient of services and they must not exceed what is necessary to attain those objectives'.

CPD is a process by which a professional demonstrates a commitment to maintaining and developing professional competence in the interests of public and patient safety.

It is the view of the Society that the requirement to undertake CPD satisfies the 'justification test' outlined in Sager. This is because

- It applies to all pharmacists wishing to pursue the pharmacy profession in Great Britain whether on a full-time or part-time basis.
- It is objectively necessary in order to ensure compliance with professional rules and to guarantee the protection of the recipient of services; and
- It does not exceed what is necessary to attain those objectives.

Recipients of professional services have a right to expect practitioners to keep their knowledge in their field of practice up-to-date. If there is an ethical (and soon to be statutory requirement) to undertake CPD for practice in GB then visiting practitioners bound by the legal and ethical framework of practice in this country should also comply with the CPD requirement.

The Society was not intending to make the requirements to comply with CPD a pre-condition for recognition/registration. In accordance with the judgement in the ECJ case of Webb C 279/80, if the 'visiting EEA practitioner' is required to undertake CPD to fulfill home state requirements, evidence of this should be submitted to the Society in accordance with future CPD rules at the point of submitting the renewal declaration for the Society to determine if this satisfies the Society's CPD scheme.

If there was no CPD requirement in the Member State of establishment, the 'visiting EEA practitioner' would be required to comply with the Society's CPD scheme and, from the point of registration, provide evidence of having done so on renewal of temporary registration.

It is difficult to see the justification in public protection terms for exempting temporary service providers from the standards regarding CPD and revalidation that practising health professionals will be required to meet under UK legislation.

(iv) Do you agree that the Regulations should give the choice to the competent authority to require automatic registration for temporary service providers?

The Society is of the view that visiting EEA pharmacists or pharmacy technicians should only be entitled to provide services if they are actually registered with the Society.

It is the Society's understanding that visiting EEA practitioners have an entitlement to provide such services and the grant of temporary registration must be administered speedily.

However it is the Society's opinion that a visiting EEA pharmacist or pharmacy technician should be entitled to be registered in Part 3 of the register and be entitled to provide services only if he has first provided the Society with the declaration plus supporting documents referred to in the Directive and the Society as the Competent Authority has undertaken the administrative task of

- confirming the authenticity of documents

and that the applicant

- possesses a pharmacy qualification which complies with the Directive requirements (or if not, the Society has followed the Directive requirements regarding check of qualifications and requiring compensation measures where appropriate)
- is legally established in a MS (with clarification of what this means) and
- is not subject to any prohibitions on his/her practice in the MS of establishment

The Society's view is that if all of these points are not satisfied, the applicant will not be registered and will not be entitled to provide services.

The DfES regulations under regulation 10 (2) states that Competent Authorities may provide either for automatic temporary registration or for pro-forma membership provided that such registration or membership should 'not delay or complicate in any way the provision of services' and should 'not entail any additional costs for the applicant'.

According to Articles 6 and 7 of the Directive there is a 2 stage process of 'recognition' of entitlement first followed by subsequent 'registration'.

In many Member States, and according to the process described in Articles 6 and 7, these 2 functions are carried out by separate organisations. For example the 'recognition' of entitlement to practise/provide a service is undertaken by the Ministry of Health or other government department and subsequently the authorisation to practise by a professional chamber. In the UK context, the Society (just like the General Medical Council and the General Dental Council) carries out both these functions. Legislation must recognise that there is a recognition process first.

The Directive accommodates the 2 stage process.

Stage 1

- An application by the prospective visiting EEA practitioner to a Competent Authority, 'the recognition' body with the declaration and supporting documents (Article 7) which must be authenticated and checked by the Competent Authority.

There would appear to be no point in requiring a declaration and documents or providing for co-operation between Competent Authorities if it is not envisaged that the documents submitted would be checked and that this will require time for a response to be received and interpreted.

Followed by Stage 2

- The sending of the declaration and supporting documents by the Competent Authority (once all administrative checks are completed) to the professional organisation for the purposes of registration (Article 6). It is this process which according to the Directive should not delay or complicate in any way the provision of services nor entail any additional costs for the service provider.

The process described in Article 6 and 7 of the Directive appears to be based on the ECJ case of Corsten C58/98. In this case a prospective service provider had to make 2 separate applications and pay 2 fees to 2 different organisations. The first application and fee was to an organization in the host Member State to obtain a certificate of recognition. Once the certificate of recognition had been received the prospective service provider had to make a further application to a professional membership body, attaching the certificate of recognition to his application and paying an additional fee. In the Court's judgement there appears to be no criticism of the first stage of recognition by a competent authority for which a fee was charged but that the requirement for a separate application to the professional chamber for authorisation with an 'additional fee' was burdensome and likely to hinder service provision.

It is the Society's view that in the UK context, regulators as both the competent authority for recognition and registration could charge a fee for recognition with registration following automatically once administrative checks had been carried out. This fee would be necessary to cover the costs involved with processing and checking such applications.

The Competent Authority must be able to administratively check the declaration and documents provided.

(v) Do you agree that service providers should be required to submit a written Declaration in advance of provision of services on renewal?

Yes

The Society would wish to check that the 'visiting EEA practitioner' continues to be 'legally established' in a Member State and check practitioner's fitness to practise history since first declaration.

The Society would also wish to receive evidence of CPD completed in the previous year in line with the Society's CPD scheme.

The Society believes that a declaration should be provided in advance of each and every period of service provision. Furthermore the declaration is to be supported with certain documents on the first provision of services or 'if there is a material change in the situation substantiated by the documents' (Regulation 12(1)(b)). How is the Society to know if there has been a 'material change'. In the interests of public and patient safety documents confirming a temporary service fitness to practise should also be provided in advance of each and every period of service provision.

(vi) Do you agree that a service provider's appeal mechanism should be the same as those relating to establishment?

DH regulations implementing the provisions for 'visiting EEA pharmacists' and 'visiting EEA pharmacy technicians' provide for an appeal against a decision to refuse to register a person on Part 3 of the Society's register as a 'visiting EEA practitioner' . The Society is concerned that if there are to be appeals, they should be handled consistently across the regulators and that regulators develop a 'common line' on appeals.

(vii) Do you agree that service providers operating on home State titles may be required, by competent authorities, to provide specified information to service recipients?

Yes Competent Authorities should require such practitioners to provide service recipients with the information described in Article 9 wherever applicable. From the point of view of consumer protection this should be mandatory and not discretionary.

(viii) Do you agree that the time period for dealing with applications for recognition under the general system regime should be a maximum of four months?

Yes
The Society has developed a paper-based assessment programme for the general system regime. The Society is confident that a comparative assessment of the applicant's qualifications and work experience against the national requirements for registration can be completed and the applicant informed of the Registrar's decision within 4 months of receipt of a complete application for registration with all supporting documents.

Do you agree that a period of three months be granted for Part 3 Chapter 2 cases?
It is our understanding that Part 3 Chapter 2 concerns roles where recognition is based on professional experience as opposed to professional qualifications. Persons wishing to practise as either pharmacists or pharmacy technicians must possess a professional qualification so these provisions do not apply.

Factual matters

A copy of the regulations on which comments on factual accuracy and typographical errors have been noted is attached.