Response to DH Consultation on The European Qualifications (Health and Social Care Professions) 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 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 of Health 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 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 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 'lawfully established' in a Member State without a clear definition of what is meant by lawful establishment.

3. The apparent ability for a 'visiting EEA practitioner' to provide a service based on his entitlement to registration even though he may not yet be registered in Part 3 of the Society's registers. The Society is concerned that legislation should ensure that there should be no provision of service without first registration with the Society. Creating a registration process, fitness to practise schemes and an appeals process would seem to be pointless if the visiting practitioner was entitled to provide services regardless of whether or not he was on the Society's register.

4. 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, prior to the first provisions of services.

   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.

5. The definition of a 'disqualifying decision'

6. Legislation must permit the registration of a 'visiting EEA practitioner' with the same conditions on practise as imposed in the home Member State.

7. The potential consequences and implications for public protection of amendments to primary and secondary legislation linked to a three part register. It is the Society's view that EEA pharmacists on Part 3 of the Society's register as a 'visiting EEA pharmacist' should be permitted to perform only the basic range of pharmaceutical activities. For those pharmacists wishing to practise in community pharmacy, this would equate to basic community pharmacy services such as dispensing and OTC sales of medicines and in hospital this would equate to activities undertaken by a newly qualified hospital pharmacist. Pharmacists on Part 3 of the Society's register should not be permitted to undertake activities which require education, training or experience beyond that required for registration.

The Society's response to the consultation questions follow.

1. Do you agree that the regulations should:

(a) Provide for a form of automatic temporary registration for temporary and occasional service providers?

Yes
Legislation must provide for registration of temporary and occasional service providers.

Entitlement to provide temporary services must be linked to registration and cannot stem from an applicant's entitlement by virtue of being lawfully established in a Member State and supplying a declaration with supporting documents.

Legislation should not permit a visiting practitioner to provide a service based on their 'lawful establishment' in a Member State without first being registered in Part 3 of the Society's registers.

Legislation must provide for a clear definition of what is meant by the practitioner being 'lawfully established'. It appears to mean more than not being prohibited from practice (even temporarily).

(b) Are you in agreement with the way in which this has been done for each profession?

No.

The Society does not believe that the procedure is in line with the provisions of Articles 6 and 7 of the Directive which in the Society's opinion describe a 2 stage process of first 'recognition' of entitlement and then 'registration'.

In many Member States 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 or registration is undertaken 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 followed by registration.

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 Articles 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 organisation 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 the requirement for a separate application to the professional chamber for authorisation with an 'additional fee' was considered 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.

Start date of entitlement to practise

The Society is concerned that, in the draft legislation, practice is permitted based on 'an entitlement' which according to the definition of 'start day' in Schedule A1 paragraph 8(4) appears to begin on the day on which the Registrar receives the declaration with supporting documents.

This completely ignores that the Society, as a regulator in the interests of public and patient safety, must administratively check that the applicant is indeed who he says he is, that he does have a qualification which falls either under 'mutual automatic

recognition' procedures or falls to be assessed as an Article 10 case and that he is indeed 'lawfully established'.

If all of these points are not satisfied the declaration and supporting documents will not be passed to Registration and the applicant will not be registered and should not be entitled to provide services. The mere receipt of documents cannot give rise to an entitlement to practise.

For the Society to be able to discharge its regulatory functions effectively, legislation must permit a period of time for these administrative checks to be completed and require that an applicant be registered before commencing to provide services in Great Britain.

The Directive itself states (Article 7(1) & (2)) that the declaration and supporting documents shall be *'provided in advance of the first provision of services'.*

The Directive does not state that the visiting practitioner is entitled to provide services from the day that the declaration and supporting documents are received by the Competent Authority.

Article 7(4) of the Directive gives the Competent Authority a maximum of one month to decide whether or not to check the qualifications for those applicants who possess qualifications which do not benefit from mutual automatic recognition. A time period must be permitted in legislation to enable the Competent Authority in the first instance to determine that an applicant does indeed possess a qualification which entitles them to 'mutual automatic recognition'.

This is unlikely to be completed on the day of receipt. Justified doubts may be raised with the Competent Authority in the Member State of establishment and responses must be received before an application can progress.

Article 6 deals with authorisation by registration with a professional organisation. This is the step which is to be automatic and is completed by the Competent Authority providing the professional body with a copy of the declaration and supporting documents.

The definition of the 'start day' in Schedule A1 paragraph 8(4) should include a cross-reference to the time limits for checks by the Competent Authority in Regulation 16 of the DfES regulations.

The DfES regulations do not specify duration of entitlement to provide services as precisely as DH regulations, there being only a requirement to provide a renewal declaration once a year.

Entitlement to provide services and registration

- It is unclear what the registration of a 'visiting EEA practitioner' actually means for the Society, the public and the practitioner, and how this differs from entitlement to provide services.

- Legislation must clarify what is meant by a visiting practitioner being entitled to provide services even if they are not on the Society's register.

- The entitlement to practise must depend on the Society as the Competent Authority checking documents and declarations and 'recognising' that an applicant is entitled. For applicants falling under Article 10 legislation does provide for qualifications to be checked. The Society contends that in all cases it is necessary to check that documents submitted are valid and up-to-date and to identify the Article 10 cases in the first place.

- The consequence of removing a practitioner from the Register needs to be clarified. Would somebody removed from the Society's register for fitness to practise reasons, for example, be able to make a new declaration of intent to provide services and then continue to provide these on the basis of being lawfully established in another Member State? All these safeguards would be pointless should the practitioner's entitlement to practise remain.

- Also, amendment of Article 42 of the Pharmacists and Pharmacy Technicians Order (page 40 of DH Regulations) gives a provision for appeals against decisions not to grant registration. This would appear to be pointless. Why would a 'visiting practitioner' appeal if their right to practise does not appear to stem from registration but from the fact that they remain 'lawfully established' in another Member State? The Society agrees that there should be an appeal against the Society's refusal to recognise an applicant's entitlement to provide temporary and occasional services, but also that the applicant's entitlement must therefore first depend upon recognition and registration with the Society.

2. Do you agree that service providers should be required to submit a written declaration?

(a) in advance of provision of services, and
(b) on renewal?

The answers to both are yes.
It is imperative that the Society knows whether (in any given year) an individual may or may not be practising in Great Britain
The Society believes that it should be able to require, in the interests of public safety, much more information than the regulations allow.

The Directive states that the *'temporary and occasional nature of the provision of services shall be assessed case by case, in particular in relation to its duration, its frequency, its regularity and its continuity'.*

The Society has been informed that the EU Commission is proposing a standard format for the written declaration. According to the EU Commission's 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.

The proposed legislation therefore makes it impossible for a judgement to be made because the written declaration in advance of service provision does not require the practitioner to provide details of the nature or duration of the services he is intending to provide.

Regulation 9(2) of the draft DfES legislation 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'. This DfES provision applies to the sectoral professions in the Article 10 cases only (paragraph 3 (5) of DfES regulations). There does not appear to be a similar provision in the DH regulations when considering applications from exempt persons who satisfy the requirements for mutual automatic recognition. Article 18 A inserted into the Pharmacists and Pharmacy Technicians Order refers to Schedule A1 (visiting pharmacists from relevant European States) but does not include a requirement to make a case by case assessment as to whether the service provision is indeed temporary and occasional in nature for persons benefiting from mutual automatic recognition. The requirement to make the case by case assessment as to whether the service provision is indeed of a temporary or occasional nature should also be included as a function of the Society in Schedule A2 – Functions of the Society under Article 64A (2).

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.

3. Do you agree that service providers should be required to supply the UK competent authority with documentation accompanying the declaration and providing proof of the service provider's nationality, legal establishment and professional qualifications?

Yes
For the Society to comply with its statutory duty to protect, promote and maintain the health and safety of the public (art 4(1) of the Pharmacists and Pharmacy Technicians Order) 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 he is to be treated as an 'exempt person' as defined in the Pharmacists and Pharmacy Technicians Order 2007
- evidence of his qualifications and
- that he is lawfully 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 or pharmacy technician 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 to an assessment of his qualification against the national requirements for registration in circumstances described under 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 or pharmacy technician and has met all the requirements for recognition.

Evidence that applicant is 'lawfully established'
The Society would wish to see a definition in the regulations of 'lawfully established'. This term appears to be crucial to the 'temporary service provider's' entitlement to provide services in Great Britain. Does the term 'lawfully 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 'lawfully 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 'lawfully 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 'lawful establishment' in a Member State which is unaware of any fitness to practise allegations or history of proceedings.

The Directive and implementing legislation only requires the person to be lawfully established for the purpose of pursuing the same profession in another Member State. 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 in that Member State 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 and be able to check the applicant's fitness to practise with all relevant Competent Authorities before permitting the practitioner to provide services in Great Britain.

Definition of 'disqualifying decision'

In Schedule A1 paragraph 8 (5)
The definition of 'disqualifying decision' in relation to a visiting practitioner must not only include a decision by a competent authority or judicial authority in the practitioner's home State but also include decisions made by the host State to suspend or remove the 'visiting EEA practitioner' from the register for either administrative or fitness to practise reasons.

It must be made clear in legislation that a pharmacist or pharmacy technician 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 being 'lawfully established' in another Member State to provide or continue to provide pharmacy services in Great Britain on a 'temporary and occasional basis'.

4. Do you agree that UK regulations should allow competent authorities to check the professional qualifications of all health and social care service providers who do not benefit from automatic recognition under the Sectoral regime? (i.e. all general systems health and social care professionals, and all Sectoral professionals subject to the general system regime under Article 10).

Yes.
The Society would wish to check the qualifications of all service providers who do not benefit from automatic recognition under the Sectoral regime. The Society supports the provision in DfES Regulation 14. This will enable the Society to verify the professional qualifications of an Article 10 pharmacist or an EEA qualified pharmacy technician prior to the first provision of services.

Continuing Professional Development

Paragraph 3 (5) Schedule A1 'Visiting Pharmacists from Relevant European States' states

> *(5) Sub-paragraphs (1) to (4) are not to be taken to prejudice the application, in relation to persons registered in the Register of Pharmacists on the basis of entitlement under sub-paragraph (1), of any other provision of this Order under which a registered pharmacist's name may be removed from the Register of Pharmacists or under which a registered pharmacist's registration in that register may be suspended.*

Could the meaning of this provision be explained? This would seem to suggest that Part 3 registrants can be required to participate in CPD, and could be removed for failing to do so.

The Directive states, in Article 5(3) 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 practising pharmacists and pharmacy technicians.

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. There appears to be an assumption that the home Member State has appropriate CPD requirements, in the absence of any assurance that other European States are as advanced as the UK in their requirements for CPD and revalidation.

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 and pharmacy technicians 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 from the point of registration, and provide evidence of having done so on renewal of temporary registration.

5. Do you agree that UK regulators should have discretion to consider breach of conditions imposed in a service provider's home State as misconduct, which could lead to FTP proceedings?

Yes

Firstly legislation should permit the Society to check with the Competent Authority in the home Member State whether any conditions have been applied to a service provider's practice in that State before he is entitled to provide services in Great Britain.

If conditions on practice are imposed on a 'visiting EEA practitioner's' practice in his home State the same conditions must appear on the face of the register in the same manner as conditions imposed on a registrant in Part 1 of the Society's registers, so that these conditions are clear to the public, patients and employers.
Conditional registration must therefore be covered in the DH regulations to enable this to happen.
It is imperative that there is equity of treatment of practising registrants irrespective of whether they are providing services in Great Britain on a temporary or occasional basis and on Part 3 of the Society's registers or whether they are established and on Part 1 of the Society's registers. Regulators should be able to apply equivalent practice restrictions to those in force in the practitioner's own home State and to regard a breach of such conditions as misconduct which could lead to fitness to practise proceedings.

If the Society is unable to do this then patients here will be less well protected than has been thought necessary in the practitioner's home State. It would also create an undesirable incentive for a health professional whose practice was restricted by conditions for fitness to practise reasons in his home State to move to another Member State as a temporary service provider until the conditions were lifted in his home State.

Additionally, the Society would wish to see a provision included in legislation clarifying that a 'visiting EEA practitioner' removed from the register for administrative reasons, or by the Society's Disciplinary Committee or suspended from the register by the Disciplinary Committee or Health Committee could not rely on his 'lawful establishment' in another Member State to provide or continue to provide pharmacy services in Great Britain on a 'temporary and occasional basis'.
The definition of 'disqualifying' decision in Schedule A1 paragraph 8 (5) should include a decision made in the host MS to remove or suspend for either administrative or fitness to practise reasons.

6. Do you agree that UK regulations should derogate (where possible under the Directive) from the applicant's right to choose the type of compensation measure, and should specify for each Sectoral health profession the regulator's preferred compensation measure?

Yes.

According to the Directive, the compensation measure, either the period of adaptation with assessments or the aptitude test, must be tailored to meet or test the 'substantially different matters' identified by the comparative assessment.

In Part 2 of Schedule 2 to the DfES draft regulations it is proposed that the compensation measure for pharmacists applying for establishment should be an adaptation period and the Society agrees with that proposal. The Society would wish to require only adaptation periods for Article 10 applicants where possible. The adaptation period with assessments under the supervision of a practising pharmacist provides a valuable safeguard before allowing an applicant to register. An adaptation period with assessments would be less onerous for the Society to administer and, we anticipate, could be accommodated within existing resources.

Pharmacy technicians will only be included in the DfES regulations once statutory registration is implemented. None of the allied health professions are listed in Schedule 2 of the DfES regulations so the Society may not be able to specify the preferred compensation measure for pharmacy technicians. However the Society would support a similar displacement of the right to choose between an adaptation period and aptitude tests for pharmacy technicians and that our preferred compensation measure would be an adaptation period as for pharmacists.

In the case of exempt persons applying for either 'visiting EEA pharmacist' status whilst not eligible for mutual automatic recognition or 'visiting pharmacy technician status' where the comparison of their qualification with the national requirements for registration reveals 'substantially different matters' the Directive only realistically permits the Society to impose an aptitude test.
To comply with the Directive the aptitude test must be designed to test only the gaps in knowledge and practice identified by the comparative assessment and must be available for applicants to sit within one month of the decision that an important difference exists between the applicant's qualification /work experience and the national requirements for registration.

It must be understood that the potential commitment here is the need to create a bespoke aptitude test, conduct a sitting, mark papers and award results - with all the ancillary arrangements for appeals of various sorts – perhaps as often as on a monthly basis. This would be a very resource intensive and a logistically demanding and complex exercise requiring substantial financial investment. It would be likely to require significant additional staffing support even if only one migrant is going though the process at a time.
A conservative costing not including venue costs and marking costs is approximately £110k per annum. This is based on the Society's experience of running the registration examination which is however only held twice a year.

Furthermore although in the Directive and draft legislation, exempt persons applying for registration as 'visiting EEA pharmacists' or 'visiting pharmacy technicians' cannot be required to pay a registration fee it is still unclear whether such applicants who will be required to undertake an 'aptitude test' can be charged an examination fee.

Requiring this category of applicant to complete an adaptation period with assessments is technically not excluded but to comply with the tight time scales it must be available and completed within one month of the decision that one is required. The Society has not fully explored the potential of providing an adaptation period as opposed to an aptitude test and will continue to explore possible solutions with various providers. The Society is however concerned that a one month period of adaptation with assessment may not be adequate to assess the identified gaps. Also finding a convenient work place centre in which to complete such an adaptation period within the short one month time frame permitted may also be unrealistic.

Amendments to other legislation

Amendment of the Medicines Act 1968

Regulation 95 (a)

The Society supports the amendment to Section 71(b) of the Medicines Act limiting the role of superintendent pharmacist to a 'person registered in Part 1 of the Register of Pharmacists…..'

The Society notes the drafting solicitor's proposed equivalent amendment to section 69(1)(a) in relation to businesses run by a sole trader or partnership and supports this. This amendment will mean that the person carrying on the business must be a Part 1 pharmacist. This will apply except where current legislation provides for non-pharmacist partners, for example in Scotland. In these circumstances provided that one partner is a pharmacist registered in Part 1 of the Register of Pharmacists then there is no prohibition on a Part 3 pharmacist forming part of that partnership.

Regulation 95(b)

In Section 132 (1) of the Medicines Act the definition of pharmacist has been amended by the Pharmacists and Pharmacy Technicians Order 2007 and will now be amended by these regulations. As suggested here a pharmacist in relation to Great Britain will mean 'a person registered in Part 1 or Part 3 of the Register of Pharmacists'. The Society has strong reservations about this but acknowledges that in order for a 'visiting EEA pharmacist' to be able to dispense prescriptions they must be included in the definition.

NHS Commissioners and employers should be made aware that the range of activities covered by sections 10, 23(2), 23(3)(b) and 52 of the Medicines Act range from the simple breaking of bulk to dispense a prescription and dispensing medication in monitored dosage systems on the one hand, to specialised activities such as the compounding of Total Parenteral Nutrition solutions, preparing cytotoxic medication and radiopharmaceuticals on the other, where the risk to patients is significantly greater. The way the legislation is drafted means that it is not possible to limit the range of activities which can be undertaken by Part 3 registrants to enable activities which are highly specialised and require considerable knowledge of UK governance issues to be excluded. Currently access to such activities can only be limited by contractual (employer) and professional (code of ethics) restrictions.

The proposed amendment to section 132 (1) means that for the purposes of the Medicines Act a pharmacist is a person who is registered in Part 1 or Part 3 of the Register of Pharmacists. This however does not square with the proposed provisions

in Schedule AI of the DH regulations in particular regulation 3(1) and (2) set out below.

> ***Registration in respect of provision of occasional pharmacy services***
>
> ***3.****—(1) A visiting practitioner is entitled to be registered in Part 3 of the Register of Pharmacists if the practitioner is entitled under paragraph 4 or 7 to provide occasional pharmacy services; and the Registrar shall give effect to the entitlement.*
>
> *(2) A visiting practitioner who is entitled under sub-paragraph (1) to be registered in Part 3 of the Register of Pharmacists, but who is not registered in that part of that register, shall be treated as registered in that part of that register.*

The Society would welcome an explanation of this provision and the proposed amendment to section 132(1). We believe that the amendment to section 132 (1) as worded would not allow a visiting EEA pharmacist to sell or supply medicines without actually being on Part 3 of the register. If this is indeed the case we would be supportive of the restriction. We are however concerned that in regulation (3)(2) of Schedule AI a visiting EEA pharmacist who is entitled to be registered but who is not registered is to be treated as if registered. Does this mean therefore that such pharmacists can sell or supply medicines even if they are not on the register? If this is indeed the case this cannot be in the interests of public and patient safety. An applicant may have supplied the declaration and documents stipulated and may contend that they are 'entitled to provide services' but it must be for the Society as the Competent Authority to confirm and acknowledge that entitlement in the first instance, having carried out all the necessary administrative checks and registering the pharmacist in Part 3 of the register.

Part 3 pharmacists and 'personal control' / 'responsible pharmacist'
Upon reflection and because of the ongoing discussions and lack of certainty regarding the skills, knowledge and experience required of a 'responsible pharmacist', the Society's view is that the 'pharmacist in personal control' or the 'responsible pharmacist' should be restricted to pharmacists on Part 1 of the Society's register. Legislation introducing the 'responsible pharmacist' will include a requirement to keep a record of who the responsible pharmacist at a particular pharmacy is at any given time. In the event of any subsequent queries the relevant responsible pharmacist could be easily identified and contacted.

A pharmacist registered in Part 3 of the register should not be the 'pharmacist in personal control' or the 'responsible pharmacist'. This is on the grounds of

- The transient nature of the role of a Part 3 registrant which is by definition 'temporary and occasional'. Such an individual may spend a significant part of their time outside Great Britain and only provide occasional pharmacy services on a locum basis. In addition the proposed amendments to Article 33 of the Pharmacists and Pharmacy Technicians Order will mean that a Part 3 registrant will be exempt from the sanction of removal from the register if they fail to comply with rules to inform the Registrar of name changes or contact details. Consequently it may prove difficult to identify and/or contact the 'responsible pharmacist' who is a Part 3 registrant.

- The responsible pharmacist will be required to establish (if not already established), maintain and review procedures to ensure the safe, effective

running of the pharmacy so far as concerns the sale and supply of medicines (something that though not currently an explicit statutory requirement, would be expected of the pharmacist in personal control) and that this will require understanding of relevant legislation, professional requirements, local and national governance arrangements and local and national prescribing policies. Such a role will require the pharmacist to meet the Society's continuing professional development (CPD) requirements which evidences their commitment to maintaining and developing professional competence in the interests of public and patient safety. In the Society's view the fact that a Part 3 registrant will potentially not be subject to the requirements contained in the Society's Code of Ethics regarding CPD means that such an individual should not be permitted to be the 'responsible pharmacist' or 'pharmacist in personal control'.

and

- because of the uncertainty in relation to the skills, knowledge and experience required to be a 'responsible pharmacist'

The Society also has similar concerns regarding equivalent scenarios in hospital pharmacy where the concept of 'personal control' and 'responsible pharmacist' do not apply unless the pharmacy department is a registered retail pharmacy. The Society would wish to see similar restrictions applied here. In effect a pharmacist registered in Part 3 of the Society's register should only be employed in community or hospital pharmacy settings in the capacity of a second pharmacist and not as the sole pharmacist in charge.

Supplementary and Independent prescribers

The Society supports the fact that no amendment is proposed to section 58(1A)(b) of the Medicines Act. This provides for pharmacists to be designated as prescribers and to administer or give directions relating to POMs. For these purposes the definition of pharmacist should continue to be limited to persons registered on Part 1 of the Register of Pharmacists. The role of supplementary/independent prescriber is an advanced role which requires specialist training from an accredited provider. The role can only be undertaken by pharmacists who have completed the training and have their specialist qualification annotated on the register.

Patient Group Directions (PGDs)

Following lengthy correspondence between the Society and drafting solicitors the Society is still of the view that only pharmacists registered in Part 1 of the register should be able to sign off PGDs. This is because signing off PGDs is an activity which will affect the practice of pharmacists and other healthcare professionals and should only be undertaken by persons who have a knowledge of relevant legislation, NHS and/or independent sector governance, local public health agenda and in depth knowledge of national and local prescribing policies and guidance contained in HSC 2000/026. Such a role will require the pharmacist to meet the Society's continuing professional development (CPD) requirements which evidences their commitment to maintaining and developing professional competence in the interests of public and patient safety. In the Society's view in the interests of public and patient safety the fact that a Part 3 registrant will potentially not be subject to the requirements contained in the Society's Code of Ethics regarding CPD means that such an individual should not be permitted to sign off PGDs.

The definition of Patient Group Direction in article 1(2) of the POM Order should be amended to restrict the signing off of PGDs to pharmacists registered in Part 1.

- **Misuse of Drugs legislation**

Consideration needs to be given to references to pharmacists in Misuse of Drugs legislation. The definition of 'pharmacist' should include pharmacists in Part 3 for the purposes of the Misuse of Drugs Regulations 2001(as amended) as pharmacists will need to be able to dispense CDs in order to provide basic pharmacy services. However, consideration needs to be given to the implications of this in light of legislative changes post Shipman, for example, pharmacists are now able to amend and supply against controlled drugs prescriptions that have a technical error in certain defined circumstances. Additionally, changes to the process for authorizing individuals to witness the destruction of CDs are planned and consideration needs to be given to whether Part 3 pharmacists should be able to witness such destruction. We suggest that there is the need for further discussion with the Home Office about this.

- **Controlled Drugs (supervision of management and use) Regulations 2006**

The definition of registered pharmacist as a 'person registered in the register maintained by the Royal Pharmaceutical Society of Great Britain' will require amending to pharmacists registered in Part 1 and 3 of the Register of Pharmacists.

- **Qualified Person Status**

In relation to the Veterinary Medicines Regulations 2006 and the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005 the definition of the pharmacist 'Qualified Person' should be restricted to pharmacists registered in Part 1 of the Society's Register of Pharmacists. This is because of the specialist nature of the role and is a view shared by the Medicines and Healthcare products Regulatory Agency.

In the Society's opinion in any legislation where reference is made to a 'responsible/qualified person' and that individual is a pharmacist the definition should be limited to a person registered in Part 1 of the Society's Register of Pharmacists.

Poisons Act 1972

It is the Society's view that pharmacists registered in Part 3 should be able to supply Part 1 poisons as defined in the Poisons List Order 1982 S.I. 1982/217. However, the Poisons Rules further restrict the supplies of certain non medicinal poisons and it is here that the Society would want to see the restriction on Part 3 pharmacists supplying those non medicinal poisons defined as Part 1 in the Poisons List and also Schedule 1 in the Poisons Rules.

Amendments to NHS (Scotland) Act 1978, NHS Act 2006 and NHS (Wales) Act 2006

The Society is of the view that the definition of 'registered pharmacist' should be extended to include those registered in Part 3 of the Society's Register of Pharmacists. This is to enable visiting EEA pharmacists to undertake basic dispensing and OTC supply of medicines. However the Society is of the view that it would not seem appropriate for a visiting EEA pharmacist to undertake non-essential services under the pharmacy contract which require education, training or experience beyond that required for registration such as Medicines Use Review for example. The Society would wish to ensure that the reference to 'registered pharmacist' in the Pharmaceutical Services (Advanced and Enhanced Services (England) Directions 2005 be amended to refer just to a pharmacist registered in Part 1 of the register. Similar considerations would need to be given to corresponding services in Scotland and Wales.

Further issues and factual accuracy

- In article 71 (b) on page 34 of DH regulations, the word 'exempt' should be removed as recital 10 of the Directive refers to third country nationals who acquired professional qualifications outside the territory of the EU and states that *'all recognition should respect in any case minimum training conditions'.* Therefore the requirement to respect minimum training requirements for recognition of pharmacy qualifications applies irrespective of whether the third country qualification is held by an 'exempt person' or a 'non-exempt' person.

- Articles 85, 86 and 87 ought to be applied to Part 3 registrants.

Article 85 which amends Article 32 (certificates of registration) of the Pharmacists and Pharmacy Technicians Order:
The Society would wish to issue Part 3 'visiting EEA practitioners' with certificates indicating they are on Part 3 of the register.

Article 86 which amends Article 33 (registrants' duties with regard to their registration entries):
The Society would want Part 3 registrants to be obliged to keep the Registrar informed of any changes in name and address and be subject to removal for failure to do so. It is imperative that in the interests of public and patient safety the Registrar has up to date information on all registrants in the event of the need to contact them in relation to fitness to practise investigations for example. Similarly in the Society's opinion Part 3 registrants should not be excluded from the provisions contained Article 33(2) of the Pharmacists and Pharmacy Technicians Order. These are administrative provisions directly linked to public and patient safety and Part 3 registrants should be removed from the register and not entitled to practise in Great Britain if they do not comply. It is not acceptable for the Society to have persons on its registers with whom it is unable to communicate.

Furthermore the Society recommends that Article 33(2) is amended to permit the Registrar to write to a 'visiting EEA pharmacist' once on Part 3 of the register to obtain information about the nature of the service they intend to provide (or have provided) and where and when the service is being (or was) provided. Failure to respond after 2 attempts should result in the temporary service provider's removal from the register.

Without these provisions the Registrar cannot comply with the obligation under Article 34 of the Pharmacists and Pharmacy Technicians Order to keep the Society's registers correct and up-to-date.

Article 87 which amends Article 35 (fitness to practise matters before registration):
In the Society's opinion Part 3 registrants should not be excluded from these provisions. The declaration before the first provision of services must require a prospective Part 3 registrant to disclose to the Registrar whether or not he has been involved in any other serious matter or whether or not he has a problem with his physical or mental health.

If a Part 3 registrant had not disclosed his involvement in a serious matter or a problem with his physical or mental health before his registration with the Society and this subsequently comes to light the Registrar should be able to remove the person from the Register.

It would seem that Article 84 paragraph 7 (page 38) and Schedule A 1 paragraph 3 (5) (page 41) of the DH regulations would permit the Society to remove a visiting practitioner if they do not undertake CPD or ignore requests for information from the Registrar, but this is unclear. It is also unclear what effect such removal from the register then has.

Professional indemnity insurance
Schedule A1 paragraph 5 (2) (a)(ii)
The requirement for providing information on professional indemnity cover only seems to concern cover in the applicant's Member State of establishment, not in the host Member State. Clarification is needed on what the Society may do should they feel that an applicant's insurance cover is not adequate or appropriate. It seems quite possible that insurance cover which was adequate in a practitioner's home State might not be adequate in Great Britain. Could legislation provide that if the prospective 'visiting EEA practitioner' has no or inadequate/inappropriate professional indemnity cover they would not be entitled to provide services in Great Britain?

In the Commission's FAQs document, the Commission refers to Article 5(3) as providing sufficient guarantee that the host Member State can require 'visiting EEA practitioners' to have adequate and appropriate professional indemnity arrangements. This is inconsistent with the Commission's approach to CPD. Both the requirement to undertake CPD and to have adequate and appropriate professional indemnity insurance are 'directly and specifically linked to consumer protection and safety'.

In Schedule A2 Directive 2005/36: Functions of the Society under Article 64A(2)
We do not understand our function in relation to Article 56(2)
What does this provision mean in practice, in particular the phrase 'examining the veracity of circumstances'? Are we required to examine the circumstances of a conviction in Germany for example? How are we to do that? Can we go behind a German Court Conviction to examine the 'veracity'? What are we to say to the German Competent Authority after our investigation? Would it not be preferable to regard a decision following a disciplinary inquiry/conviction just like a certificate of conviction ie evidence that the misconduct/offence occurred etc and not go behind it?

The Royal Pharmaceutical Society of Great Britain (Registration) Rules 2007
Part 3 of the Registration Rules and in particular rules 6, 7 and 8 would need to be amended to cover temporary service providers.

The Impact Assessment of European Qualifications (Health and Social Care Professions) Regulations 2007 prepared by the DH

In this document the DH assumes that *' the total temporary register set up costs for all regulators, including amendments to websites and databases will be in the region of £30K' .*
The DH estimates that there will be about 400 migrants per annum seeking to register using the temporary provision of services arrangements and that *'the total recurrent annual cost falling to the regulatory bodies will be around £12K per annum'.*
It is unclear from this statement whether the estimated £12K running cost is per regulator or for all regulators.

The Society is concerned that this is a gross underestimate of the costs involved. As indicated in response to question 6 above the costs to the Society for setting up a bespoke aptitude test alone could be in the region of £110K.

Temporary service provision is not only new to the General System regime but also new for pharmacists. Pharmacists unlike doctors, nurses and dentists did not have provisions for temporary service providers in the old pharmacy sectoral Directives. Temporary registration therefore cannot fit within our existing systems. To accommodate 'visiting EEA practitioner status' the Society will be required to set up a separate third part to each of the registers. Additional costs will be incurred in structural changes to the data base framework which supports the registers and in training staff and the Society's Statutory Committees.

The Society would wish to charge applicants for 'visiting EEA practitioner status' a recognition fee which will cover the administrative costs of verifying the 'entitlement' to provide services as 'registration' should be at no 'additional cost' and must be automatic or pro forma.

The cost of recognition and registration should not be borne by registrants on either Part 1 or Part 2 of the Society's Registers.