29 May 2015


Introduction

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public and, in particular, those members of the public who use or need the services of pharmacy professionals or services provided by a registered pharmacy.

We regulate pharmacists and pharmacy technicians in community and hospital settings. We also regulate practice within academia, research, public health, commissioning, management, industry and other settings where the public rely indirectly, but no less significantly, on the professionalism and competence of pharmacy professionals in a wide range of non-clinical roles. We also set standards for registered pharmacies.

Our principal functions include:

- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises;
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD);
- setting and promoting standards for the safe and effective practice of pharmacy at registered pharmacies;
- establishing fitness to practise requirements and monitoring pharmacy professionals’ fitness to practise; and
- dealing fairly and proportionately with complaints and concerns.
We welcome the opportunity to comment on the Draft statutory instrument: European Union (Recognition of Professional Qualifications) Regulations 2015; and the Draft guidance for competent authorities implementing Directive 2005/36/EC [mutual recognition of professional qualifications]. Please find our comments below.

**Draft regulations**

Our comments are on the attached draft regulations however we have expanded on a number of these below.

**Professional traineeship**

Paragraph (1) of draft Regulation 7 states “Subject to (2) a competent authority in the United Kingdom must, when considering an application to carry out professional services where access is conditional on completion of a professional traineeship, recognise professional traineeships that have been carried out in a third country or another relevant European state.”

Paragraph 1 of Article 55a of the Directive does not require us to ‘recognise’ professional traineeships carried out in a third country but only to ‘take into account’ professional traineeships carried out in a third country.

It would be helpful if the implementing legislation reflected the wording of the Directive here.

**European professional card for temporary and occasional provision of services**

Draft regulation 24(10) recognises that the sectoral professions (with the exception of architects) have public health or safety implications. We therefore believe it is very important for us to be involved in the decision as to whether an applicant for the European professional card (EPC) for temporary and occasional service provision is to follow the automatic or General System route to recognition and whether they should have their qualification checked by us prior to being permitted to provide temporary and occasional services here. In the EU database for pharmacists the default position for whether a prior check of qualifications under article 7(4) of the Directive is permissible is set at ‘No’. This should be changed to ‘Yes’. We would want to exercise the discretion to determine whether or not to check a qualification prior to the first provision of services. If we determined that an applicant was entitled to automatic recognition of their qualification we would not check the qualification, but in all cases that fell under the General System of recognition including third country qualified applicants who had had their qualification recognised and were fully entitled to practise their profession in the recognising member state we would wish to
check the qualification against our national qualification requirements before permitting the holder to provide services here for the first time.

In addition Article 20(5) of the Implementing Regulation enables a competent authority to revoke an EPC after it has been issued. Could such a provision be included in the draft Regulations?

In our view this is an important patient safety measure in cases where a temporary and occasional EPC is issued by the home member state under the automatic route, but we believe that the applicant falls under the General System and there should have been a prior check of qualifications by us first. In these cases we should be able to revoke the issued EPC and follow the prior check of qualification process before we issue a new EPC (after the individual has completed the required compensation measure where relevant).

**Compensation measures - Regulations 46, 47 & 48**

We currently have a derogation in the implementing legislation from an EEA qualified pharmacist’s right to choose between an aptitude test or a period of adaptation training with assessments.

As such, where a compensation measure is required under the General Systems, we currently require EEA pharmacists to successfully complete an adaptation period with assessments. We would like this derogation to continue when an applicant has a qualification that is only one level below the level we require. The period of adaptation with assessments provides assurance that the applicant has acquired the knowledge missing by directed self-learning and is able to demonstrate that they can apply this in practice under the supervision of a registered pharmacist.

When we are considering qualifications that are more than one level lower than the qualification we require we would wish to explore the opportunity of applying a derogation again from the applicant’s right to choose but in these cases to specify an aptitude test rather than an adaptation period with assessment. This is because in these cases a more formal assessment of the knowledge element that we have identified as missing would be required to provide assurance that an applicant has indeed acquired the depth of knowledge necessary for safe and effective practice.

Would it be possible to continue with the current derogation and require an adaptation period with assessment if the qualification was only one level lower than that required by us but change the derogation to an aptitude test when the qualification was more than one level lower?
Additionally we would wish to apply for a derogation for European qualified pharmacy technicians and be able to stipulate a period of adaption training with assessments. The UK pharmacy technician qualification comprises a GPhC approved knowledge qualification and a GPhC competency qualification (at the level described by Directive article 11( c )). Both are vocational qualifications completed and assessed while working under the supervision of a registered pharmacist. An adaptation period with assessment is therefore a more appropriate compensation measure than an aptitude test.

Draft Guidance

General system recognition page 7

Box 1 under step 4 (‘Is the duration of the applicant’s education and training at least one year less than that required by the profession in the UK?’)

Has this criterion not been removed by Directive 2013/55/EU?

Step 5
‘An adaptation period not exceeding 3 years or an aptitude test may be required. A combination of these is not allowed (Art 14) (Reg 48)

It is our understanding that a combination in some circumstances is permitted see Directive Article 14(3), the paragraph following paragraph (b) and draft regulation 48(2).

The references that follow on page 7 should be to draft regulation 48 and not to draft regulation 49.

Section 1.7 on page 12 – compensation measures

In our view, reference should be made here to the fact that some competent authorities have a derogation which allows them to require an adaptation period, rather than allowing the applicant a choice of an aptitude test or an adaptation period, in accordance with regulation 48(1)(b) and Schedule 3, Part 2 of the draft Regulations?

Section 1.7 continued on page 13

The draft Guidance states ‘The competent authority must set the ‘rules’ for the operation of an adaptation period. This means that the authority needs to formalise any general administrative procedures with which the applicant or the mentor/supervisor must comply.’
Our policy for the adaptation period with assessment is to require a period of supervised practice with assessment in full compliance with our pre-registration training requirements, under the supervision of a pharmacist tutor and at premises approved as a pre-registration training establishment.

In our draft guidance on language competency we are proposing that General System EEA pharmacists who are required to complete a period of pre-registration training under the supervision of a tutor have to first provide evidence of their knowledge of the English language before they begin this training. This is because we want to make sure that their English language competence meets our requirements before they start working in a supervised capacity with patients, carers, their families and other healthcare professionals.

We believe our approach would be compliant.

**Section 1.9 on page 14 – Requirements other than qualifications**

*The provisions setting out the criteria relating to requirements other than qualifications are detailed in Annex VII of the Directive. Those documents referred to in point 1d), e) and f) of Annex VII of the Directive have a three months validity as these contain information which may change rapidly:*

We would welcome clarity as to whether this should also apply to the attestation in 1 g) introduced by Directive 2013/55/EU?

Our view is that the validity of this attestation should also be limited to three months.

**Section 4.5 on page 19 – Checking of qualifications**

The draft Guidance states that *‘Only for the first provision of service for professions having public health and safety implications (cases listed in Schedule 2 of SI XXXX/XXXX) can a check be made of the service provider’s qualifications – this is only the qualification and not professional experience’*

We think this should be clarified.

Professions having public health or safety implications also include the sectoral professions as provided by draft regulation 24(10).

Although we agree that we are only to check the qualifications, where a substantial difference is found between the applicant’s qualification and the qualification we require, professional experience + knowledge, skills & competences acquired through lifelong learning are to be taken into account.
Section 4.6 on page 21 – Requirement for further information

In our view the second paragraph on checks needs to be updated in line with Article 7(2)(e) of the Directive as the exception does not only apply to the security sector – but also to the health sector and professions related to the education of minors etc.

Section 6.3 on page 30 – Language Skills

The Health Care and Associated Professions (Knowledge of English) Order 2015 provides that European qualified applicants must provide us with evidence that they have the necessary knowledge of English for safe and effective pharmacy practice after we have recognised their qualification, but before they are entitled to be registered.

It would therefore be helpful if the last sentence in this section about Language testing not being ‘used systematically or be standardised’ was revised to recognise that article 53(3) of the Directive distinguishes between professions with implications for patient safety, where language controls may be imposed, and other professions, where language checks can only be conducted where there is a serious and concrete doubt about the sufficiency of the professional’s language knowledge.

Annex 3 Declaration pursuant to Article 7 concerning the temporary provision of services

Question one refers to the form having up to 10 sections. The annex only contains sections 1 to 5 with sections 6-10 missing. Some of the information missing is:

- A declaration regarding knowledge of language necessary for practising the profession
- Information about professional qualifications
- An attestation confirming the absence of temporary or final suspensions from exercising the profession and of criminal convictions (for professions in the security sector, in the health sector and professions related to the education of minors, including in childcare and early childhood education, where the Member State so requires for its own nationals).

Question 4.3 - In our view this should be amended to one year to comply with Article 5(1)(b) of the Directive.