



## Consultation response form

Transposition of revised Mutual Recognition of Professional Qualifications (MRPQ) Directive 2005/36/EC Amendments to health and care regulators' legislation

A CONSULTATION ON THE HEALTH SPECIFIC AMENDMENTS TO THE DIRECTIVE

### About you

**You do not have to tell us this information if you do not want to.**

**Please fill in and/or tick the appropriate response.**

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The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties. However, the information you send us may need to be passed on to colleagues within the UK Health Departments and/or published in a summary of responses to this consultation.

I do not wish my response to be published in a summary of responses

**Are you responding (please select one):**

As a member of the public

As a health or social care professional

On behalf of an organisation

**If you are responding on behalf of an organisation, please supply details:**

The General Pharmaceutical Council  
25 Canada Square , London E14 5LQ

The General Pharmaceutical Council (GPhC) is the independent regulator for pharmacists, pharmacy technicians and pharmacy premises in Great Britain. It is our role to protect, promote and maintain the health, safety and wellbeing of patients and the public who use pharmacy services in England, Scotland and Wales.

Our core statutory functions include:

- setting the standards of education and training which pharmacists and pharmacy technicians must meet in order to join our register and to remain registered throughout their professional life
- registering pharmacists and pharmacy technicians and setting the standards of conduct and performance which they must meet to stay on our register
- setting standards which must be met by the owners of registered pharmacies and the pharmacists who act as superintendents in company-owned pharmacies
- registering pharmacies which meet those standards and inspecting them to check that they continue to do so
- taking action when our standards are not met – typically through Fitness to Practise (FtP) proceedings and enforcement action

## Consultation Questions

### **1) Are there any further legislative amendments, other than those set out in the draft European Qualifications (Health and Social Care Professions) Regulations 2015, which you think are required as a result of the changes to the Directive?**

We are grateful that the consultation draft has made amendments to article 28 (registrants' duties with regard to their entries) and article 30 (fitness to practise matters before entry or renewal of an entry) of the Pharmacy Order 2010 so that both of these provisions will in future apply to visiting practitioners registered in Part 4 and 5 of the Register.

We would wish to see the following legislative amendments made:

- 1) We would welcome if this opportunity to make amendments to the Pharmacy Order also included an amendment to article 42(1)(a).

This requires the GPhC to set standards of proficiency for the safe and effective practice of pharmacy which it is necessary for a person to reach before being registered as a pharmacist or pharmacy technician but specifically excludes all European qualified pharmacy professionals. In the case of European qualified pharmacy professionals under the General Systems (i.e. those that fall to be considered as 'appropriately qualified' by virtue of article 21(1)(c) or article 22(1)(b)) we do check that they meet the standards of proficiency required as part of the comparative assessment of their qualifications against our national requirements for registration. The exclusion in art 42(1)(a) should therefore only apply to those qualified by virtue of art 21(1)(b), i.e. to European pharmacists under the automatic route where the assurance of proficiency is provided by the home Member State.

- 2) In new article 42A 'Professional traineeships carried out in other relevant European States, etc', the amendment should clarify that 'the person' in this provision is an 'exempt person'.
- 3) We recall that the European Commission at a recent training event confirmed that the revised RPQ Directive would not apply to Switzerland as Switzerland had not yet agreed to adopt it. This would explain the revised interpretation of 'relevant European State' in regulation 2 and the 'transitional and saving provisions' at Regulation 78 (3) of the European Union (Recognition of Professional Qualifications) 2015 ("General Systems Regulations"). Should a similar interpretation of 'relevant European State' be added to each article implementing a provision of the revised RPQ to limit its application to an EEA State only?
- 4) We would recommend using wording in draft regulation 42A(3) that follows article 55a(1) of the Directive and which is repeated in regulation 7 (1) of the European Union (Recognition of Professional Qualifications) 2015 ("General Systems Regulations"). This would separate the requirement to 'recognise professional traineeship' carried out in another relevant European state from the

requirement to 'take account of professional traineeship' carried out in a third country to avoid ambiguity.

- 5) 42A(1) provides - *"If a prospective registrant is required to carry out a professional traineeship in the United Kingdom in order to be appropriately qualified under article 21 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacists) or article 22 (pre-entry requirements in respect of qualifications and additional education, training or experience: pharmacy technicians), a professional traineeship of an equivalent standard that has been carried out in another relevant European State is treated as meeting that requirement."* We disagree with this interpretation of the revised RPQ Directive provisions. The Directive does not require professional traineeship completed in another European State to replace the entire period of professional traineeship we require in order for an applicant to be regarded as being appropriately qualified under article 21 or 22. On the contrary, article 55a(1) of the Directive permits Member States to set a reasonable limit on the duration of the part of the professional traineeship which can be carried out abroad. We therefore request that the GPhC is given the power in the Pharmacy Order 2010 to impose a reasonable limit on the duration of the part of such traineeship completed abroad along similar lines to the provision in regulation 7(4) of the General Systems Regulations 2015.
- 6) Article 55a(2) of the Directive states that any recognition of professional traineeship shall not replace any requirements in place to pass an examination in order to gain access to the profession. We request that explicit provision along lines similar to the provision in regulation 7(3) of the General Systems Regulations 2015 is included in the Pharmacy Order.
- 7) Temporary and occasional (T&O) service provision & the EPC

The existing Directive process requires European qualified pharmacists wishing to provide temporary and occasional (T&O) services in GB to provide us with a declaration of their intention to provide such services together with supporting documents confirming their qualification and legal establishment in their home member state. From a procedural perspective we check the documents provided to determine whether the qualification awarded to the European pharmacist does indeed permit the holder to benefit from automatic recognition and whether they are indeed legally established to practise as a pharmacist in their home Member State without any restrictions on their practice. It is therefore currently for us to decide whether the individual is entitled to be registered in Part 4 of our register and provide services here or whether they should first be required to pass an aptitude test before being permitted to do so.

Under the EPC process for T&O service provision it is for applicants and the home Member State to determine rights to automatic recognition of qualifications and therefore registration in Part 4 of our register. This will no longer be a decision for us to make. In our view this presents serious risks to patient safety and means that we will be unable to assure patients and the public that persons registered in Part 4 of our register are

competent and fit to practise. The draft regulations allow us to remove a person from the register if their EPC becomes invalid (see Schedule 2A, para 15(3)), so it is logical that we should not register someone whose card is invalid from the outset. We strongly urge DH to include provisions to enable us to refuse to register an individual who has been issued with an EPC for T&O service provision by their home Member State in circumstances where we have concerns that the EPC has been issued in error.

Further minor drafting comments on the proposed amendments to the Pharmacy Order are attached.

**2) Do you think that a pharmacist trainee should take their practical training during their course or at the end of their course?**

We have always supported the view that the six month period of practical training should be undertaken towards the end of the 5 year Directive compliant pharmacy qualification. In our view the value of the six month period of practical training may be diminished if completed at an earlier stage during the qualification.

**3) Do you have any comments on any of the changes in the section above or, where applicable, how these have been inserted into the draft European Qualifications (Health and Social Care Professions) Regulations 2015?**

We have no comments to make concerning the expansion of activities that can be undertaken by a pharmacist. In our view the revised Directive continues to make explicit that the list of activities in Article 45(2) is a minimum set of activities that holders of Directive compliant pharmacy qualifications must be able to gain access to and pursue. Other activities can be pursued in addition to these. No amendments appear to have been made to the Pharmacy Order and we don't think that any are required. This is because of the broad interpretation in article 3(2) of what constitutes practising as a pharmacist.

**4) Do you have any comments on the Department's draft European Qualifications (Health and Social Care Professions) Regulations 2015 in relation to the EPC? Are there any further consequential amendments that you think need to be made?**

Under paragraph 1 'Application', Part 1, Schedule 2A we suggest making it explicit that this Schedule applies to an 'exempt' person (P).

It is our understanding (see response to Question 1) that the EPC provisions will not apply to Swiss nationals as Switzerland has not adopted the revised RPQ. As such the 'relevant European State' in Schedule 2A should be interpreted as applying to EEA States only.

We believe that in paragraph 11 of Part 3 of Schedule 2A it should be made explicit that the EPC for establishment only covers the 'recognition' of qualification and that 'P' would

be required to make an application for registration in accordance with articles 23 and 24 of the Pharmacy Order as amended by the Knowledge of English Order 2015<sup>1</sup> before they would be entitled to be registered in Part 1 of the register and practise as a pharmacist.

In Part 5 of Schedule 2A we are of the view that similar specific provisions should be included here as in Schedule 2 that entitlement to registration in Part 4 ceases if P becomes established as a pharmacist in the UK or if a disqualifying decision has been made by either the home or host Member State.

Again we would strongly urge DH to include provisions to enable us to refuse to register an individual who has been issued with an EPC for T&O service provision by their home Member State in circumstances where we have concerns that the EPC has been issued in error.

Further comments on the proposed amendments to the Pharmacy Order are attached.

##### **5) Do you think there are any potential issues with the introduction of the EPC in relation to the health care professions that have been selected by the Commission?**

In all of our responses to numerous consultations over the years we have continued to reiterate our strongly held view that in the interests of patient safety the EPC should not apply to pharmacists. For example, in our response to the European Commission's consultations on the RPQ Directive [March<sup>2</sup> & Sept 2011<sup>3</sup> we explained that in jurisdictions such as the UK where every healthcare regulator has real-time, web based publicly searchable registers of professionals who are registered and fit to practise there was no added benefit in introducing the EPC. An issued EPC in cases of establishment could only be used by the holder to evidence 'recognition of qualification' and not that the holder had been granted access to the profession. The EC's decision to provide a facility via their Internal Market Information (IMI) System for the public and employers to check the validity of a printed document presented to them purporting to be an issued EPC can only lead to confusion and to potentially fraudulent EPCs in circulation.

Our position was also restated in our response to DH's call for evidence for the EU balance of competence review [[March 2013](#)<sup>4</sup>].

In our response to the [BIS's consultation on the transposition of the revised RPQ](#)<sup>5</sup> into UK regulations we emphasised the fact that the risk of confusion was further increased in automatic recognition T&O service provision cases where an EPC issued by the home

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<sup>1</sup> The Health Care and Associated Professions (Knowledge of English) Order (SI 2015/806)

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[pharmacyregulation.org/sites/default/files/European%20Commissions%20Public%20Consultation%20on%20the%20Recognition%20of%20Professional%20Qualifications%20Directive%20GPhC%20response.pdf](http://pharmacyregulation.org/sites/default/files/European%20Commissions%20Public%20Consultation%20on%20the%20Recognition%20of%20Professional%20Qualifications%20Directive%20GPhC%20response.pdf)

<sup>3</sup> [pharmacyregulation.org/sites/default/files/GPhC%20Response%20to%20EC%20Green%20paper%20110920.pdf](http://pharmacyregulation.org/sites/default/files/GPhC%20Response%20to%20EC%20Green%20paper%20110920.pdf)

<sup>4</sup> [pharmacyregulation.org/sites/default/files/GPhC%20response%20to%20the%20DH%20call%20for%20evidence%20-%20EU%20balance%20of%20competence%20review.pdf](http://pharmacyregulation.org/sites/default/files/GPhC%20response%20to%20the%20DH%20call%20for%20evidence%20-%20EU%20balance%20of%20competence%20review.pdf)

<sup>5</sup> [pharmacyregulation.org/sites/default/files/bis\\_consultation\\_response\\_form\\_-\\_transposition\\_of\\_the\\_revised\\_mutual\\_rec\\_.pdf](http://pharmacyregulation.org/sites/default/files/bis_consultation_response_form_-_transposition_of_the_revised_mutual_rec_.pdf)

member state will not only mean that the European pharmacist has a qualification that has been recognised but also grants them access to pursue the pharmacy profession in the UK and hence automatic registration with us and the Pharmaceutical Society of Northern Ireland.

Additionally, the stated aim of the EPC is to speed up and facilitate the mobility of professionals. We are not aware of any evidence to suggest that the mobility of pharmacists as a professional group within the EEA has been adversely affected by the existing Directive application processes. We therefore do not see that the EPC brings any benefits. On the contrary we see very real risks to patient safety from the introduction of the EPC for pharmacists especially in the case of the EPCs for T&O service provision under the automatic route for recognition. Under paragraph 8 on page 6 of the consultation document it is stated that 'The regulators control access to regulated professions, professional and vocational titles and professional activities.' But in the case of an EPC for T&O services under the automatic route the control of access to provide T&O pharmacist services in Great Britain and the use of the professional title 'pharmacist' will no longer be controlled by the GPhC. Entitlement to registration in Part 4 of our register, use of the title 'pharmacist' and provision of T&O services here will be determined by the competent authorities in the home Member States.

To mitigate the risks to patients safety that this route to registration in Part 4 of our register presents we strongly urge DH to include provisions to enable us to refuse to register an individual who has been issued with an EPC for T&O service provision by their home Member State in circumstances where we have concerns that the EPC has been issued in error.

**6) Do you agree with the Department's interpretation of what should constitute an alert in relation to healthcare professionals?**

Yes

**7) Do you think that it would be helpful for the Department to provide healthcare specific guidance for the regulatory bodies to complement the BIS guidance?**

Yes - we believe that DH should provide healthcare specific guidance to complement the BIS guidance. It would also be helpful to see the final version of the BIS guidance as only a preliminary draft version was circulated with BIS's consultation in Spring 2014.

**8) Is there anything that you would like us to include in healthcare specific guidance?**

In the EC's training event on the EPC we made a suggestion that the process under article 4c of the Directive for the issuance of a EPC for T&O services under the automatic route (where there is no prior check of qualifications under article 7(4) of the Directive) include a role for us as host MS. In these applications the home MS has 3 weeks within which to validate and authenticate documents submitted by an applicant to support their application

for an EPC for T&O services under the automatic route. We have requested permission to access the application file during this 3 week period. This may enable us to liaise with the home MS competent authority to confirm that the applicant is legally established in the home MS to practise as a pharmacist with no restrictions on their practice and whether the selected route to registration in Part 4 of the Register is indeed correct. We believe that in the interests of patient safety it is imperative that we are able to do this prior to the home MS issuing the EPC.

If a legislative solution cannot be found to enable us to refuse to register the holder of an issued EPC for T&O services under the automatic route we believe it is imperative that some procedural solution is found to enable the GPhC to be involved in the decision as to whether a prospective service provider does indeed have a qualification or work experience that entitles them to automatic recognition or not.

It would be helpful if DH guidance could include a role for us as the host competent authority in the issuance of the EPC in these circumstances. This could promote mutual cooperation between Member State competent authorities and would arguably be in compliance with the provisions of article 4 of the EC's Implementing Regulation<sup>6</sup>. The penultimate paragraph of this provision states that ... 'if the applicant has not indicated the right regime, within the one week of receipt of the EPC application the competent authority of the home MS shall advise the applicant to resubmit under the applicable regime. Where appropriate, the competent authority of the home member State shall first consult the competent authority of the host member State.'

**9) Are there any protected characteristics that you feel may be effected, either positively or negatively, by these changes?**

No

**10) Are there any potential monetary impacts (either positive or negative) that you think we need to be aware of?**

We are of the view that there are potential negative monetary impacts for the following reasons:

Currently, we have no European qualified pharmacists wishing to provide T&O services here and we assume this is because the possibility is not known widely. This will change from the 18th January 2016 when the EPC website on the Internal Market Information (IMI) system will make this route to service provision very clear to all prospective applicants. Under article 36 of the Pharmacy Order "fees in connection with entry" we cannot require prospective T&O service providers to pay an application for entry or renewal fee to Parts 4 or 5 of our Register. This can only have a negative impact on

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<sup>6</sup> Commission Implementing Regulation (EU) 2015/983 of 24 June 2015 on the procedure for issuance of the EPC and the application of the alert mechanism pursuant to Directive 2005/36/EC of the European Parliament and of the Council

income.

We are grateful that express powers to charge a reasonable fee for administering the EPC process have been proposed in new article 33A of the Pharmacy Order.

In the interim, to reduce any negative impact on income, we plan to charge fees for administering the EPC using our powers under article 65 of the Pharmacy Order. Article 65 contains a general fee-making power for the Council, which has been delegated to the Chief Executive.

Also the cost of developing on-line application processes to comply with the Directive requirements will have financial implications for us as will the additional staff costs incurred in planning and re-engineering our systems to comply with the added bureaucracy associated with the EPC.