

Consultation on proposed amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008

March 2015

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About the Pharmaceutical Society

The Pharmaceutical Society of Northern Ireland is the regulatory body for pharmacists in Northern Ireland.

Our primary purpose is to ensure that practising pharmacists are fit to practise, keep their skills and knowledge up to date and deliver high quality safe care to patients.

It is the organisation's responsibility to protect and maintain public safety in pharmacy by:

- Setting and promoting standards for pharmacists' admission to the Register and for remaining on the Register;
- Maintaining a publicly accessible Register of pharmacists, and pharmacy premises;
- Handling concerns about the fitness to practise of registrants, acting as a complaints portal and taking action to protect the public; and
- Ensuring high standards of education and training for pharmacists in Northern Ireland.

Why are we consulting?

In order to ensure the Pharmaceutical Society NI can fully implement the policy aims of the Department of Health (England) (DH) Health Care and Associated Professions (Knowledge of English) Order 2015, which applies on a UK-wide basis, the Council and the Department of Health, Social Services and Public Safety (DHSSPS) considers it necessary to amend the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008. We are therefore undertaking this joint consultation exercise together with DHSSPS in order to introduce this amendment.

To help ensure that the Pharmaceutical Society NI and DHSSPS are taking the correct approach to this issue, the Council is consulting all stakeholders on the proposed approach and amendment.

Following conclusion of the consultation the Council will work with the DHSSPS to bring forward an amendment if appropriate to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008. These amendments will be considered by the Northern Ireland Assembly.

How to respond to this Consultation

We welcome your response to this consultation and have listed some questions to assist you. In order to help us analyse responses, we would strongly encourage you to complete the response template provided.

Please note that as this is a joint consultation exercise your responses will be shared with DHSSPS.

Responses should be sent by post, fax or email to:

Consultation on proposed amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008.

Pharmaceutical Society of Northern Ireland

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Tel: 028 9026 7935
Fax: 028 9043 9919

Email: Mark Neale, consultation coordinator mark.neale@psni.org.uk

Accessibility of information

If you are having difficulties accessing the documentation or you need us to make adjustments in order to be able to respond to this consultation, please contact us and we will do our best to address the issue.

If you wish your response to remain confidential you should indicate this in your response and the Pharmaceutical Society NI will generally respect this request. However, the information you provide may be subject to disclosure under the Freedom of Information Act 2000.

Consultation period

The consultation will run for 8 weeks from 2 March 2015 closing at 12 noon on 27 April 2015.

When the consultation closes, we will analyse the responses we receive which will be taken into account by Council of the Pharmaceutical Society NI and DHSSPS when making their final decision.

Consultation questions

We would welcome any views you may wish to submit on the questions outlined below. It is important that you provide reasons for your comments, where possible, in order for the Council of the Pharmaceutical Society NI and DHSSPS to consider the rationale for your views. We have provided a response template to complete, which is available on the website: <http://www.psn.org.uk/publications/consultations/>

1. Do you agree with the general approach of the Pharmaceutical Society of Northern Ireland to this issue?

Yes	No	Unsure
Further comments		

2. Do you agree with the proposed amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 as it is worded?

Yes	No	Unsure
Further comments		

3. Do you have any further comments on the proposal?

Yes	No	Unsure
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What is this consultation about?

In May 2010 the Coalition Agreement stated that 'we will seek to stop foreign healthcare professionals working in the NHS unless they have passed robust language and competence tests' in order to assure patient safety and quality care in the UK.

DH, in agreement with DHSSPS, has, through the Health Care and Associated Professions (Knowledge of English) Order 2015, amended the Pharmacy (Northern Ireland) Order 1976 to strengthen the Pharmaceutical Society NI's powers around English language controls for pharmaceutical chemists in Northern Ireland. The Order also strengthens powers around English language controls for the Nursing and Midwifery Council (NMC), the General Dental Council (GDC) and the General Pharmaceutical Council (GPhC).

Any applicant, including European applicants, can now be asked by the Registrar of the Pharmaceutical Society NI to supply evidence, information or documents about

their English ability or an applicant can be asked to sit an English language test and provide evidence of results, prior to the applicant being placed on the register.

The implementation of these English language controls must be taken forward in accordance with European law and in particular the Mutual Recognition of Profession Qualifications (MRPQ) Directive. The recently revised MRPQ Directive prevents regulatory bodies imposing English language controls prior to recognising European healthcare professionals' qualifications. Language controls must be fair and proportionate.

In addition, the MRPQ Directive sets certain time limits concerning the time it takes for a Registrar of a Regulatory body to process applications to the Register for European citizens. The time limits are three months for automatic recognition cases and four months for general systems cases. In relation to the Pharmaceutical Society NI these time limits are included in the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008.

As the time taken to provide evidence of English language competency is outside of the control of the Registrar, an anomalous situation has arisen for the Pharmaceutical Society NI whereby, in order to meet the time limits as set out in the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008, the Pharmaceutical Society NI may not be able to meet its obligations to test a European applicant's English language competency, potentially putting at risk public safety.

To deal with this issue for other Regulators, DH, through the Health Care and Associated Professions (Knowledge of English) Order 2015 introduced provision for the NMC, GDC and GPhC so that the time limits can be suspended during any period when a European applicant has been requested to supply evidence, information or documents about English language competency, or during which such an applicant has been asked to sit a test and provide evidence about the results of it.

It is necessary to introduce equivalent provision for the Pharmaceutical Society NI and therefore an amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 is now required.

Language Controls stages for NMC, GDC and GPhC as introduced by the Knowledge of English Order 2015

1. Registrar receives European application to the register;
2. MRPQ Directive time limits for application process starts (3 months for automatic recognition/4 months for general systems cases) ;
3. Registrar acknowledges applicants qualification and seeks evidence of English language competency;
4. MRPQ Directive time limits suspended;
5. Proof of English language competency accepted by Registrar;
6. Time limits for application process re-started;
7. Applicant registered.

Current Language Controls stages for Pharmaceutical Society NI – without proposed amendment

1. Registrar receives European application to the register;
2. MRPQ Directive time limits for application process starts (3 months for automatic recognition/4 months for general systems cases);
3. Registrar acknowledges applicants qualifications and seeks evidence of English language competency;
4. Applicant is afforded time to provide evidence of language competence; time limits would **not** be suspended during this period;
5. Proof of English Language competency accepted by Registrar;
6. Applicant registered.

Options

The Pharmaceutical Society NI considers that two options are therefore open:

1. Do nothing;
2. Ask the Department of Health, Social Services and Public Safety to approve an amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008, to allow for the required time period to be suspended during any period when a European applicant has been requested to supply evidence, information or documents about English language competency, or during which such an applicant has been asked to sit a test and provide evidence about the results of it.

The Pharmaceutical Society NI considers that option one could create a risk of registering a person about whom there were language concerns in order to comply with the timeframe established in the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 in situations where it has not been possible, for whatever reason, to complete the test within the stipulated time.

The Pharmaceutical Society NI and DHSSPS therefore consider option two to be the best and only option available.

Proposal

In consultation with DHSSPS, the Pharmaceutical Society NI proposes the following amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 be placed before the Northern Ireland Assembly.

Proposed amendment

2. (1) Regulation 2 of the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 is amended in accordance with paragraphs (2) to (4).
- (2) At the beginning of paragraph (11) insert “Subject to paragraph (11A),”.
- (3) After paragraph (11) insert—
 - “(11A) In calculating any period of time for the purposes of paragraph (11), the following are to be disregarded—
 - (a) any period which begins on the date on which the registrar makes a request under Article 8AA(4) of the Order and ends on the date on which E complies with the request; or
 - (b) any period which begins on the date on which the Registrar requires E to undergo an examination or other assessment under Article 8AA(6)(a) of the Order and ends on the date on which E complies with the requirement under Article 8AA(6)(b) of the Order.”.
- (4) After paragraph (12) insert-
 - “(13) A document that is requested under Article 8AA(4) or (6)(b) of the Order is not to be treated as missing for the purposes of this regulation.”.

Notes on proposed amendment:

The time limits outlined above begin when a “complete” application is received by the Registrar – a complete application is one which includes all the documents listed in Annex VII to the MPRQ Directive¹. These **do not** include documents demonstrating English language ability.

The proposed new provisions in the amendment to the Registration of Pharmaceutical Chemists (Exempt Persons) Regulations (Northern Ireland) 2008 will **not** change the list of documents which constitute a “complete” application, thus ensuring that the time limit will continue to start to run as soon as the regulatory body is in receipt of a “complete” application as defined in MRPQ, but will rather introduce suspensions in the time limit, where appropriate, to enable English language checks to take place.

A full set of the draft amendment regulations is attached at **Appendix 1**.

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005L0036-20140117&from=EN>