EXPLANATORY MEMORANDUM TO

THE GENERAL PHARMACEUTICAL COUNCIL (AMENDMENT OF MISCELLANEOUS PROVISIONS) RULES ORDER OF COUNCIL 2016

2016 No. 1008

1. Introduction

1.1 This explanatory memorandum has been prepared by Department of Health and is laid before Parliament by Command of Her Majesty. This Order is being simultaneously laid before the Scottish Parliament.

2. Purpose of the instrument

2.1 The Order approves Rules made by the General Pharmaceutical Council ("the GPhC") which amend the General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010 (which are set out in the Schedule to S.I. 2010/1615); the General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010 (which are set out in the Schedule to S.I. 2010/1616) and the General Pharmaceutical Council (Registration) Rules 2010 (which are set out in the Schedule to S.I. 2010/1617). The Rules which this Order approves, are contained in the Schedule to the Order, and these have been made by the GPhC under powers taken in the Pharmacy Order.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None.

Other matters of interest to the House of Commons

3.2 As this instrument is subject to the negative procedure and has not been prayed against, consideration as to whether there are other matters of interest to the House of Commons does not arise at this stage.

4. Legislative Context

4.1 The Health Care and Associated Professions (Knowledge of English) Order 2015 (S.I. 2015/806) ("the Knowledge of English Order") and the Health Care and Associated Professions (Indemnity Arrangements) Order (S.I. 2014/1887)("the Indemnity Order") amended the Pharmacy Order 2010/231 ("the Pharmacy Order"). The Knowledge of English Order amendments enable the GPhC to apply language controls, where appropriate, to pharmacists and pharmacy technicians from relevant European states; and the Indemnity Order enables the GPhC to make rules enabling the provision of information to the registrar about indemnity arrangements that a pharmacist or pharmacy technician must have in place in order to comply with the obligation set out in the Pharmacy Order, for all practising registrants to have indemnity arrangements in force at all times in relation to themselves. Further miscellaneous amendments have been made to the Statutory Committees and their Advisers Rules in order to avoid conflicts of interest in relation to common membership on their panels.

4.2 This Order approves Rules set out in the Schedule to it, to make changes to the following sets of rules, using the powers inserted by the Knowledge of English Order and the Indemnity Order, and other powers contained in the Pharmacy Order to make other miscellaneous amendments. The rules amended by the instrument are:

- The General Pharmaceutical Council (Registration) Rules 2010 (SI 2010/1617) ("the Registration Rules")
- The General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010 (SI 2010/1615) ("the Fitness to Practise Rules")
- The General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010 (SI 2010/1616)("the Statutory Committees and their Advisers Rules")

4.3 The Rules contained in the Schedule to this Order amend the Fitness to Practice Rules using powers in the Pharmacy Order 2010, introduced by the Knowledge of English Order, to require pharmacists and pharmacy technicians, where appropriate, to undertake an examination or other assessment of knowledge of the English language, and to provide evidence of the same on registration.

4.4 The Indemnity Order made some consequential amendments to the Registration Rules. The amendments proposed here set out in more detail the information to be provided by applicants or registrants and the action that may be taken if a registrant does not comply with the indemnity requirements.

4.5 The Rules contained in the Schedule to this Order also amend the Registration rules using powers in the Pharmacy Order, substituted by the Indemnity Order, to include rules on the information to be provided by a person seeking registration or restoration or at any time for registrants, to the Registrar to determine at any time, whether there is compliance with duty for all practising pharmacists (or as the case may be, pharmacy technicians) to have in place an indemnity arrangement in force and in relation to themselves.

4.6 Under article 66(4) of the Pharmacy Order 2010, the Rules in the Schedule to this Order cannot come into force until approved by the Privy Council.

5. Extent and Territorial Application

5.1 The extent of this instrument is the United Kingdom with the exception of Northern Ireland.

5.2 The territorial application of this instrument is the United Kingdom with the exception of Northern Ireland.

6. European Convention on Human Rights

6.1 The Department of Health has made the following statement regarding Human Rights:

6.2 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

What is being done and why

Indemnity arrangements

7.1 The Health Care and Associated Professions (Indemnity Arrangements) Order 2014 ('Indemnity Order') amended the Pharmacy Order 2010 so as to implement the Finlay Scott review recommendations[1] that there should be a requirement across regulated health professions for practising health professionals to have insurance or indemnity arrangements as a condition of registration; and article 4(2)(d) of Directive 2011/24/EC[2] which requires member states to have systems of professional liability cover or similar in place in respect of cross-border healthcare for patients receiving treatment in their member state.

7.2 The purpose of the policy is to ensure that people have access to appropriate redress in the unlikely event that they are negligently harmed by the health professional in the course of their treatment. The majority of regulated health professionals are unaffected by this policy as they already have personal cover, an indemnity arrangement as a benefit of membership of a professional body or that provided by their employer.

Knowledge of English

7.3 In May 2010 the Coalition Agreement set out that 'we will seek to stop foreign healthcare professionals working in the NHS unless they have passed robust language and competence tests'[3] in order to assure patient safety and quality of care in the UK.

7.4 All international applicants are already required to provide evidence of knowledge of language before they can be registered with the appropriate healthcare regulatory body in the UK. However the implementation of language controls for European Economic Area (EEA) applicants must be in accordance with European law and in particular the Mutual Recognition of Professional Qualifications (MRPQ) Directive[4]. The MRPQ Directive prevents regulatory bodies from imposing language controls prior to recognising European healthcare professionals' qualifications. It also requires language controls to be fair and proportionate rather than being automatically applied to all.

7.5 In November 2014, the Government consulted on behalf of the Devolved Administrations on proposals to enable the relevant regulatory body to introduce language controls for EEA nurses, midwives, dentists, dental care professionals, pharmacists and pharmacy technicians, to ensure they have a sufficient knowledge of the English language to enable them to practise safely in the UK. This followed earlier changes to the legislation governing the General Medical Council which introduced language controls for doctors in April 2014.

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[1] https://www.gov.uk/government/publications/independent-review-of-the-requirement-to-have-insurance-or-indemnity-as-a-condition-of-registration-as-a-healthcare-professional

[2] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0024

[3] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/78977/coalition_programme_for_government.pdf

[4] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02005L0036-20140117&from=EN

7.6 The Health Care and Associated Professions (Knowledge of English) Order 2015 amends the Pharmacy Order 2010 to give the GPhC powers to introduce proportionate language controls in relation to EEA applicants following recognition of their professional qualification, but before registration.

7.7 In addition, the Order amends the regulators' fitness to practice powers, to introduce a new 'impairment of fitness to practice' for not having the necessary knowledge of English which will allow the GPhC to initiate fitness to practise proceedings in cases where a pharmacist or pharmacy technician's knowledge of the English language may pose a serious risk to patient safety. They have also been given powers to require an individual to undergo an English language test as part of fitness to practice proceedings.

7.8 The Knowledge of English Order also requires the GPhC to publish guidance setting out the evidence, information or documents that an applicant or registrant may provide to demonstrate that they have the necessary knowledge of English for safe and effective practice as a pharmacist or a pharmacy technician. The GPhC consulted on draft guidance in September 2015[5].

Consolidation

7.9 The GPhC has no plans formally to consolidate the principle Rules but it does make informal consolidated versions of its rules.

8. Consultation outcome

8.1 On 24 September 2015, the GPhC consulted on changes to its rules, as set out at 4.1 of this document. The consultation process ended on 17 December 2015.

8.2 The GPhC received 73 responses to its consultation. These responses came from pharmaceutical professionals and members of the public.

8.3 The GPhC's analysis of its consultation shows that responses were broadly supportive of the proposed changes. The GPhC therefore decided to go ahead with the changes set out in its consultation. A copy of the consultation can be found online at: (http://www.pharmacyregulation.org/rules-and-guidance-consultation). A hard copy can be obtain by writing to the GPhC at:

General Pharmaceutical Council

25 Canada Square

London

E14 5LQ

9. Guidance

9.1 Alongside the consultation on amendments to rules, the GPhC consulted on draft guidance about the evidence, information and documents that may be provided by an applicant or registrant for the purpose of satisfying the registrar that they have the necessary knowledge of English, and the process by which the registrar will determine whether he is satisfied that the person has this knowledge. The report of that

[5] http://www.pharmacyregulation.org/rules-and-guidance-consultation

consultation can be found here - http://www.pharmacyregulation.org/previous-consultations and a copy of the final guidance can be found here http://www.pharmacyregulation.org/about-us/what-we-do/legislation/pharmacy-order-2010-and-rules. Hard copies can be obtained from the GPhC at the above address.

10. Impact

10.1 A registrant that works for a charity or voluntary organisation could be required to provide evidence of their indemnity arrangements. If these arrangements included cover by their employer, the charity or voluntary sector organisation would need to give the registrant information on this cover, which the registrant would then provide to GPhC. The GPhC will not request evidence of indemnity cover from registrants on a routine basis; therefore we consider the costs on the charitable or voluntary sector to be minimal.

10.2 In relation to the public sector, there will be a cost to the GPhC of implementing indemnity and language controls for EEA professionals. There would also be some one-off costs associated with updating GPhC systems, producing guidance and communicating the changes to registrants. The Department of Health's impact assessment for the Indemnity Order estimated the transition cost for all affected regulatory bodies as £716k, with annual recurring costs of £80k.

11. Regulating small business

11.1 The legislation applies to activities that are undertaken by small businesses.

11.2 However, as the Indemnity Order does not place any requirements on employers, any minimal costs placed on them will not constitute a direct impact.

11.3 In terms of the Knowledge of English Order, the changes are unlikely to have a significant monetary impact. The costs are likely to fall to either the GPhC, in terms of additional administration; or the individual EEA applicant, in terms of the costs of any language tests.

12. Monitoring & review

12.1 The GPhC will continue to review its Rules.

13. Contact

13.1 Professional Standards Branch at Department of Health email: RegulationsPQSharedMailbox@dh.gsi.gov.uk can answer any queries regarding the instrument.