Consultation on draft amendments to rules

The GPhC (Registration) Rules 2010 The GPhC (Fitness to Practise and Disqualification etc.) Rules 2010, and The GPhC (Statutory Committees and their Advisers) Rules 2010

September 2015

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The deadline for responding to this consultation is

Thursday 17 December 2015.

Consultation on draft amendments to rules

1. Overview

The GPhC is consulting until **Thursday 17 December 2015** on changes we are proposing to our rules. The main purpose of these proposals is to implement the statutory requirements for a registrant to have an appropriate indemnity arrangement in force and to have the knowledge of English necessary for safe and effective practice, as conditions of their registration with us. The changes would also introduce measures to avoid conflicts of interest arising from common membership of Appeals Committee and Fitness to Practise Committee panels.

Our purpose is to protect patients and the public by setting and upholding standards in pharmacy. With this aim in mind, we are proposing changes to the rules governing our registration processes, our fitness to practise proceedings, and our statutory committees. The proposed amendments would affect:

The General Pharmaceutical Council (Registration) Rules 2010 (SI 2010/1617)

The General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010 (SI 2010/1615)

The General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010 (SI 2010/1616)

Current versions of these rules can be found on our website at www.pharmacyregulation.org/about-us/what-we-do/legislation/pharmacy-order-2010-and-rules. These consolidated versions are not official text; users should consult an official version of the legislation for the purpose of interpreting and applying the law.

Alongside this consultation, we are also consulting on draft guidance about the evidence, information and documents that may be provided by an applicant for the purpose of satisfying the Registrar that they have the necessary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 consultation on the guidance can be found on our website at www.pharmacyregulation.org/rules-and-guidance-consultation.

2. The consultation process

The Council has considered carefully a range of information and evidence as part of its consideration of this consultation on changes to rules. However, we want to test our thinking and the Council wants to make the best possible decisions when it meets to consider making changes to our rules. We need help from those with information and views, to test both our overall approach to implementing these changes as well as the specific proposals and the potential impact or benefits of the changes. Please let us know what you think about any or all of the proposals described in this document.

The consultation will run for 12 weeks and will close on Thursday 17 December 2015. During this time we would welcome feedback from individuals and organisations. We will send this document to a range of stakeholder organisations, including professional representative bodies and employers, as well as patients' representative bodies. We hope they will review this consultation and consider responding.

You can download more copies of this document from our website or you can ask us for a copy of the document in an alternative format (for example, in larger type or in another language).

How to respond

You can respond to the consultation in a number of different ways:

You can fill in the questionnaire at the end of this document or complete one online at www.pharmacyregulation.org/rules-and-guidance-consultation

If you fill in the questionnaire, please send it to:

- Email consultations@pharmacyregulation.org with the subject 'Amendments to rules consultation'
- Address
 Amendments to rules consultation response
 Rules lead, Strategy directorate
 General Pharmaceutical Council
 25 Canada Square
 London
 E14 5LQ

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself, please send them to:

Email feedback@pharmacyregulation.org

or

Address
 Amendments to rules consultation process
 Strategy directorate
 General Pharmaceutical Council
 25 Canada Square
 London
 E14 5LQ

Please do not send consultation responses to these addresses.

Report of this consultation

Once the consultation period is completed, we will analyse the responses we receive and the Council will take these into account when making its decisions. We will also publish a summary of the responses received and an explanation of the decisions taken. This will be available on our website www.pharmacyregulation.org

The Council is scheduled to consider making the proposed changes to rules at its meeting in April 2016 and the changes would come into force once their parliamentary processes had been completed.

3. Background

We are 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 patients and the public who use pharmacy services in England, Scotland and Wales.

Our main roles include:

- approving qualifications for pharmacists and pharmacy technicians, and accrediting education and training providers
- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development (CPD)
- establishing and promoting standards for the safe and effective practice of pharmacy at registered pharmacies
- establishing fitness to practise (FtP) requirements, monitoring pharmacy professionals' FtP and dealing fairly and proportionately with complaints and concerns

The main pieces of legislation governing the GPhC are the Pharmacy Order 2010 (SI 2010/231) and the Medicines Act 1968 (c. 67). More detailed provisions relating to our regulatory functions are set out in statutory instruments called 'rules'. The changes we are proposing to our rules would be made under the Pharmacy Order.

The full text of the proposed changes to our rules can be found in appendix 1.

4. Indemnity arrangements

- 4.1 The Health Care and Associated Professions (Indemnity Arrangements) Order (SI 2014/1887) was made last year. It amended the Pharmacy Order 2010 so as to implement a requirement for practising health professionals to have insurance or indemnity arrangements as a condition of registration. It also implemented article 4(2)(d) of Directive 2011/24/EC requiring member states to have in place systems of professional liability cover or similar in respect of cross-border healthcare for patients receiving treatment in their member state.
- 4.2 Registrants were already under an obligation, under article 32 of the Pharmacy Order, to have appropriate indemnity cover in force. The GPhC's standards also require registrants to ensure that all their work, or work for which they are responsible, is covered by appropriate professional indemnity cover. The Indemnity Arrangements Order defined 'appropriate cover' as cover against liabilities that may be incurred in practising as a pharmacist or pharmacy technician which is appropriate, having regard to the nature and extent of the risks of practising as such.
- This cover must be in force by the time the person begins to practise (rather than, as previously, on the date of registration). The indemnity requirements do not apply to visiting pharmacists or pharmacy technicians from relevant European states. Visiting practitioners are required to provide a declaration which includes details of the indemnity arrangements they have in place. They are registered in part 4 (for visiting pharmacists) or part 5 (for visiting pharmacy technicians) of our register based on their legal establishment in their home member state.
- 4.3 The Indemnity Arrangements Order made some consequential amendments to the Registration Rules. The amendments proposed to the rules here build on these to 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.

5. Knowledge of English

- 5.1 The Health Care and Associated Professions (Knowledge of English) Order (SI 2015/806) was made in March 2015. It amends the Pharmacy Order to strengthen the GPhC's powers to introduce fair and proportionate language controls and to require EU applicants to provide evidence of their knowledge of the English language, following recognition of their professional qualification but before registration.
- 5.2 The Knowledge of English Order requires the GPhC to consult on and publish guidance setting out the evidence, information or documents that an applicant may provide to demonstrate that they have the necessary knowledge of the English language for safe and effective practice as a pharmacist or a pharmacy technician. We are consulting on this draft guidance alongside this consultation on changes to our rules. You will find this on our website at www.pharmacyregulation.org/rules-and-guidance-consultation.
- 5.3 The requirement to have the necessary knowledge of English for safe and effective practice applies to all applicants and registrants. Any person who is refused registration on the grounds that they have failed to satisfy the Registrar that they have the necessary knowledge of English will have a right of appeal.
- 5.4 The Knowledge of English Order creates a new category of impairment of fitness to practise relating to English language competence. This will allow us to initiate fitness to practise proceedings in cases where a pharmacy professional's knowledge of the English language may pose a serious risk to patient safety.

6. Amendments to the GPhC Statutory Committees and their Advisers Rules

6.1 The amendments proposed in this section would affect The General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010 (SI 2010/1616).

Common membership of Fitness to Practise Committee and Appeals Committee panels

6.2 The GPhC has three statutory committees:

Investigating Committee – this committee considers allegations that a registrant's fitness to practise is impaired and decides whether to refer the case to the Fitness to Practise Committee for a full inquiry. The committee also considers whether the GPhC should institute criminal proceedings under any of its enforcement powers.

Fitness to Practise Committee - this committee makes decisions in cases where a registrant's fitness to practise may be impaired. It also considers allegations that a pharmacy owner should be disqualified and that pharmacy premises should be removed from the register.

Appeals Committee – this committee considers appeals against decisions relating to registration or to approval of education providers, as listed in article 39 of the Pharmacy Order.

- 6.3 The Statutory Committees and their Advisers Rules allow persons to be members of both the Fitness to Practise Committee (FtPC) and the Appeals Committee. These committees also share a list of reserve panellists. This provides flexibility and helps panellists to maintain their skills but it is possible that potential conflicts of interest could arise from common membership of the committees' panels i.e. if the same person or persons served on both a FtPC panel and an Appeals Committee panel to consider the same matters. We want to amend the rules to prevent this happening.
- 6.4 There are a few situations where the Appeals Committee and the FtPC could be considering the same issues:
 - i. The Appeals Committee may request advice from the FtPC under rule 9(1)(d) of the Appeals Committee Rules (SI 2010/1614).
 - ii. The Registrar may seek the advice of the FtPC about the fitness to practise of an applicant for registration (Registration Rules 10(8) & (10)). The FtPC would not make the final decision on the application but would advise the Registrar, who would then decide whether to grant the application. If the Registrar refused the

application, the applicant could appeal that decision to the Appeals Committee (art 39(1) (b), Pharmacy Order).

- iii. The Registrar may determine that a registrant's entry in the register has been fraudulently procured or incorrectly made (art 29(3), Pharmacy Order). A registrant's entry may also be removed if their fitness to practise was impaired at the time the entry was made (art 30, Pharmacy Order). Under rules 19 and 20 of the Registration Rules, a registrant on whom a Notice of Intention to Remove [from the register] has been served may request a hearing. If a hearing is requested, the Registrar must refer the matter to the FtPC. The FtPC would make findings of fact and advise the Registrar but it is the Registrar who would decide whether to remove the person from the register. The Registrar's decision could then be appealed to the Appeals Committee (art 39(1)(i)-(j), Pharmacy Order).
- 6.5 Draft rule 2 of the Amendment of Miscellaneous Provisions Rules would prevent common membership of Fitness to Practise Committee and Appeals Committee panels where this could give rise to a potential conflict of interest.

Question 1

 Do you agree with the proposal to prevent common membership of Fitness to Practise and Appeals Committee panels where this could give rise to a conflict of interest?

7. Amendments to the GPhC Registration Rules

7.1 The amendments proposed in this section would affect the General Pharmaceutical Council (Registration) Rules 2010 (SI 2010/1617). Most of the proposed changes are to implement the requirements for a registrant to have an appropriate indemnity arrangement in force and to have the knowledge of English necessary for safe and effective practice, as conditions of their registration with us.

Draft rule 3 - Duty to provide information about indemnity arrangements: registrants

- 7.2 This would insert a new rule 8A in the Registration Rules requiring registrants, on receipt of a notice from the Registrar, to provide information for the purposes of determining whether an indemnity arrangement is in force which provides appropriate cover in relation to them (draft rule 8A(1)). The information would need to be provided within seven days or any longer period that the Registrar specifies (draft rule 8A(3)). Draft rule 8A(2) provides a non-exhaustive list of information that may be required.
- 7.3 Registrants would also have to inform the Registrar within seven days if they cease to have an indemnity arrangement in force which provides appropriate cover (draft rule 8A(5)).

7.4 If a registrant did not provide the information required about their indemnity cover, the Registrar would be able to: refuse to renew their registration; remove their entry from the register, or treat the failure as misconduct for fitness to practise purposes (draft rule 8A(4)).

Question 2

 Do you agree with the proposed duty for registrants to provide information about their indemnity arrangements?

Draft rule 4 – Entry in the register

Indemnity arrangements

- 7.5 This would amend rule 10 of the Registration Rules (entry in the register). An applicant for registration would be required to declare that they understand that:
 - they cannot practise unless they have an indemnity arrangement in force which provides appropriate cover;
 - they must inform the Registrar within seven days if they cease to have such an arrangement in force; and
 - their entry in the register may be removed if such an arrangement is not in force (draft rule 4(2)).
- 7.6 Applicants would complete a self-declaration that they have, or will have, an indemnity arrangement in force which provides appropriate cover (see current Registration Rule 10(3)(ga)). The exception to this would be where an applicant had been removed from the register previously for failing to comply with the indemnity requirements. Such applicants would be required to provide a copy of their insurance policy or other indemnity arrangement, together with a description of the activities they intend to undertake when practising (draft rule 4(5)). An applicant who completed a self-declaration would also need to supply this additional evidence if requested by the Registrar (draft rule 4(6)).

Crown copyright and the front cover of a UK passport

- 7.7 In 2012, the Registration Rules were amended such that applicants for registration who supplied a certified copy of their UK passport as evidence of identity should not include the front page of their passport in the certified copy. This change was made as some applicants had found it difficult to obtain a certified copy of the whole of their passport because solicitors had declined to certify a copy including the front page, which bears the Royal Coat of Arms, on the ground that this was protected by Crown copyright.
- 7.8 The amendment was made but the Parliamentary Joint Committee on Statutory Instruments took the view that the rule should have stated that a copy of the passport with or without the front cover could be supplied. While understanding the reasoning behind the change, the Committee commented that the people authorised to certify copies of passports under the rules (notaries, solicitors or Commissioners for Oaths) could be assumed to have sufficient legal expertise to form their own views on the risks of including the front page. Their view was that, if a solicitor is content to certify a copy of the whole of a passport, that has no adverse effect on its value as evidence, which is what the need for certification is aimed at. We therefore propose to amend the rules such that a certified copy of a UK passport may or may not include the front cover (draft rule 4(3)(a) and (4)).

Knowledge of English

7.9 An applicant for registration would also be required to provide evidence of having the necessary knowledge of English (draft rule 4(3)(b)-(c)). The Council will be obliged to consult on and publish guidance about the evidence, information and documents that may be provided by an applicant 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 (see art. 23A, Pharmacy Order, inserted by the Knowledge of English Order). The consultation on this guidance is running alongside this consultation on amendments to rules. You will find this on our website at www.pharmacyregulation.org/rules-andguidance-consultation.

Question 3

 Do you agree with the proposed changes on applications for entry in the register?

Draft rule 5 – Renewal of an entry in the register

- 7.10 An applicant for renewal would have to specify whether they have, or will have, an indemnity arrangement in force providing appropriate cover. They would also have to declare that they understand that:
 - they cannot practise unless they have an indemnity arrangement in force which provides appropriate cover;
 - they must inform the Registrar within seven days if they cease to have such an arrangement in force; and
 - their entry in the register may be removed if they do not have such an arrangement in force (draft rule 5(2)(a)-(b)).
- 7.11 An applicant for renewal would have to specify whether they hold evidence demonstrating that they have the necessary knowledge of English (draft rule 5(2)(c)-(d)).
- 7.12 Applicants would also need to supply additional evidence if reasonably required by the Registrar for the purposes of verifying the information in or determining the application (draft rule 5(3)-(4)).

Question 4

 Do you agree with the proposed changes on applications for renewal of an entry in the register?

Draft rule 6 – Annotations made to an entry in the register

- 7.13 This would amend rule 12 of the Registration Rules, which relates to applications for an annotation to an entry in the register, denoting a specialisation. An applicant for an annotation would have to specify whether, if the annotation were to be made, they would have an indemnity arrangement in force providing appropriate cover (draft rule 6(2)(b)).
- 7.14 If the applicant had been removed from the register previously for failing to comply with the indemnity requirements, they would have to provide a copy of their insurance policy or other indemnity arrangement, together with a description of the activities they intend to undertake when practising (draft rule 6(3)).

Question 5

 Do you agree with the proposed changes on applications for an annotation to an entry in the register?

Draft rule 7 – Renewal of an annotation made to an entry in the register

- 7.15 This would amend rule 13 of the Registration Rules, which relates to applications for renewal of an annotation to an entry in the register, denoting a specialisation. An applicant for renewal of an annotation would have to specify whether, if the annotation were renewed, they would have an indemnity arrangement in force providing appropriate cover (draft rule 7(2)).
- 7.16 If the applicant did not provide any supporting documents, information or evidence required, the application would be refused (draft rule 7(3)).

Question 6

 Do you agree with the proposed changes on applications for renewal of an annotation to an entry in the register?

Draft rule 8 – Restoration of an entry in the register

- 7.17 This would amend rule 16 of the Registration Rules, which relates to applications for restoration of an entry in the register i.e. an application to return to the register after an absence of up to a year. An applicant for restoration to the register would be required to declare that they understand that:
 - they cannot practise unless they have an indemnity arrangement in force which provides appropriate cover;
 - they must inform the Registrar within seven days if they cease to have such an arrangement in force; and
 - their entry in the register may be removed if they do not have such an arrangement in force (draft rule 8(2)(b)).
- 7.18 Applicants for restoration would have to declare that they have, or will have, an indemnity arrangement in force which provides appropriate cover (see Registration Rule 16(3)(a)(i)(ab)). An exception to this would be where an applicant had been removed from the register previously for failing to comply with the indemnity requirements. Such applicants would have to provide a copy of their insurance policy or other indemnity arrangement, together with a description of the activities they intend to undertake when practising (draft rule 8(3)).

7.19 An applicant for restoration would have to specify whether they hold evidence demonstrating that they have the necessary knowledge of English (draft rule 8(2)(d)).

Question 7

 Do you agree with the proposed changes on applications for restoration of an entry in the register?

Draft rule 9 – Restoration of an annotation to an entry in the register

- 7.20 This would amend rule 17 of the Registration Rules, which relates to applications for restoration of an annotation to an entry in the register, denoting a specialisation. An applicant for restoration of an annotation would have to specify whether, if the annotation were restored, they would have an indemnity arrangement in force providing appropriate cover (draft rule 9(2)).
- 7.21 Any applicant who had been removed from the register previously for failing to comply with the indemnity requirements would have to provide a copy of their insurance policy or other indemnity arrangement, together with a description of the activities they intend to undertake when practising (draft rule 9(3)).

Question 8

 Do you agree with the proposed changes on applications for restoration of an annotation to an entry in the register?

8. Amendments to the GPhC Fitness to Practise and Disqualification etc. Rules

8.1 The amendments proposed in this section would affect the General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010 (SI 2010/1615). The proposed changes are to implement the requirement for a registrant to have the knowledge of English necessary for safe and effective practice, as a condition of their registration, and to allow us to initiate fitness to practise proceedings in cases where a pharmacy professional's knowledge of the English language may pose a serious risk to patient safety.

Draft rule 10 - Interpretation

8.2 This would amend rule 2 of the Fitness to Practise and Disqualification Rules, which defines terms used in these rules. This would provide a definition of a 'knowledge of English allegation' (an allegation that a person's fitness to practise is impaired by reason of not having the necessary knowledge of English for safe and effective practice).

Draft rule 11 – Initial action in respect of allegations

This would amend rule 6 of the Fitness to 8.3 Practise and Disqualification Rules (initial action in respect of allegations). Under this rule, the GPhC's investigations of a knowledge of English allegation could include requiring the person concerned to undertake an examination or assessment of their knowledge of English and to provide evidence of the result within a specified period (draft rule 11(2)(b)). Draft rule 11(3) gives more detail of the procedure to be followed. If the Registrar issued such a direction and the person concerned failed to comply with it, the Registrar could treat that failure as an allegation of misconduct and refer it, with or without the knowledge of English allegation, directly to the Fitness to Practise Committee (draft rule 11(4)-(5)).

Draft rule 12 – Notices of referral and documents to be supplied to persons concerned

8.4 This would amend rule 7 of the Fitness to Practise and Disqualification Rules (notices of referral and documents to be supplied to persons concerned). When a knowledge of English allegation was referred to the Investigating Committee, the Registrar would be required to send the person concerned a copy of the Council's guidance about the evidence, information and documents that may be provided 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 (draft rule 12(2)). The person would also be informed of the committee's power to require them to undertake an examination or assessment of their knowledge of English (draft rule 12(3)).

Draft rule 13 – Applications for restoration

8.5 This would amend rule 8 of the Fitness to Practise and Disqualification Rules (applications for restoration). This amendment would mean that persons who had been removed from the register by the Fitness to Practise Committee and who then applied for restoration (article 57, Pharmacy Order) may need to provide evidence demonstrating that they have the necessary knowledge of English, as part of their evidence of their fitness to return to practice (draft rule 13(2)). The procedure by which the person may be required to undertake an examination or assessment of their knowledge of English is covered in draft rule 13(3).

Draft rule 14 – Procedures of the Investigating Committee

8.6 This would amend rule 9 of the Fitness to Practise and Disqualification Rules (procedures of the Investigating Committee). Under this rule, the Investigating Committee, when considering a knowledge of English allegation, could direct the person concerned to undertake an examination or assessment of their knowledge of English and to provide evidence of the result to the Registrar within a specified period. If the person concerned failed to comply with such a direction, the Investigating Committee could refer that failure to the Fitness to Practise Committee as an allegation of misconduct, with or without the knowledge of English allegation.

Draft rule 15 – Action upon referral of an allegation

8.7 This would amend rule 13 of the Fitness to Practise and Disqualification Rules (action upon referral of an allegation).

Under this rule, the Fitness to Practise

Committee, when considering a knowledge of English allegation, could direct the person concerned to undertake an examination or assessment of their knowledge of English and to provide evidence of the result within a specified period (draft rule 15(2)). The procedure to be followed is covered in draft rule 15(3).

Draft rule 16 – Evidence

8.8 This would amend rule 24 of the Fitness to Practise and Disqualification Rules (evidence). The amendment would allow the Fitness to Practise Committee, when determining whether a person's fitness to practise is impaired by not having the necessary knowledge of English, to take into account any failure by that person to undertake an examination or assessment of their knowledge of English and to provide evidence of the result of that examination or assessment

Question 9

 Do you agree with the proposed changes to fitness to practise proceedings in cases where it is alleged that a pharmacy professional does not have the knowledge of English necessary for safe and effective practice?

Question 10

 Do you have any other comments you want to make?

The draft GPhC (Amendment of Miscellaneous Provisions) Rules 2015 are at appendix 1.

How to respond

The consultation asks a series of questions, which are set out here.

You can respond to the consultation in a number of ways:

- go to our website at www.pharmacyregulation.org/rules-andguidance-consultation and respond online.
- email consultations@pharmacyregulation.org
- complete the consultation response form and send it to:

Draft amendments to rules consultation response Rules lead, Strategy directorate General Pharmaceutical Council 25 Canada Square London E14 5LQ

You can add extra pages if you need more space to respond. Please say which questions any extra pages apply to.

Responses must be received by **Thursday 17 December 2015**

Unless you ask us to, we will not acknowledge your response.

How we will use your response

Your response to this consultation will be used to help us make decisions on changes to our rules. Following the consultation, we will publish a report summarising what we heard. We may quote parts of your response in that report or in other documents but we will make quotes from individuals anonymous.

We may publish your response in full unless you tell us otherwise. If you want your response to remain confidential, you should explain why you believe the information you have given is confidential. However, we cannot guarantee that confidentiality can be maintained in all circumstances.

The GPhC may need to disclose information under access to information legislation (usually the Freedom of Information Act 2000, the Environmental Information Regulations 2004 and the Data Protection Act 1998).

If your response is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.

Any diversity monitoring information you give us will be made anonymous and used to review the effectiveness of our consultation process. It will not be part of a published response.

Consultation response form

Response to the consultation on draft amendments to rules of the General Pharmaceutical Council

Publishing responses

If you want your response to remain confidential, you should explain why you regard the information you have provided as confidential. However, we cannot give an assurance that confidentiality can be maintained in all circumstances.

maintained in all circumstances.
☐ Please remove my name from my published response
Please tell us if you have any concerns about us publishing any part of your response:

Background questions

First, we would like to ask you for some background information. This will help us to understand the views of specific groups, individuals and organisations and will allow us to better respond to those views.

Are you responding:

- As an individual? please go to section A
- On behalf of an organisation? please go to section B

Please tell us your:

Section A - Responding as an individual

Name:	Section B. Personding on behalf
Address:	Section B - Responding on behalf of an organisation
Email:	
Where do you live?	Please tell us your:
□ England	Name:
□ Scotland	Job title:
□ Wales	Organisation:
□ Northern Ireland	Address:
□ Other (please give details)	Email:
United (please give details)	A contact name for enquiries:
Are you responding as:	Contact phone number:
□ A pharmacy professional – Please go to section A1	
☐ A member of the public	Is your organisation:
□ Other (please give details)	☐ A pharmacy organisation
	☐ A non-pharmacy organisation
	. , ,
Section A1 Pharmacy	Please choose the option below which best
Section A1 - Pharmacy	describes your organisation:
professionals	 □ Body or organisation representing professionals □ Body or organisation representing patients or the
	public
Are you:	□ Body or organisation representing a trade or
☐ A pharmacist	industry
□ A pharmacy technician	☐ Independent pharmacy (community pharmacy
	with 1-5 premises)
Please choose the option below which best	□ Multiple pharmacy (community pharmacy with
describes the area you mainly work in:	6-99 premises)
□ Community pharmacy	☐ Large multiple (community pharmacy
□ Hospital pharmacy	with 100 or more premises)
□ Primary care organisation	□ NHS organisation or group
□ Pharmacy education and training	□ Research, education or training organisation
Pharmaceutical industry Other (alacas give data; la)	☐ Government department or organisation
□ Other (please give details)	□ Regulatory body
	☐ Other (please give details)

If you work in community pharmacy, are you:

A pharmacy owner

A self-employed locum

An employee

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Consultation questions

We are particularly interested in your views on the following points, although we welcome comments on any issues that you want to raise about the draft amendments to the rules.

amei	ndments to the rules.	(see sections 7.2-7.4 of the consultation document)	
1.	Do you agree with the proposal to prevent common membership of Fitness to Practise and Appeals Committee panels where this could give rise to a conflict of interest? (see sections 6.1-6.5 of the consultation document)	☐ Yes☐ No☐ Don't know☐ Do you have any further comments in response to question 2?	
	□ No		_
	□ Don't know		
	Do you have any further comments in response to question 1?		

Do you agree with the proposed duty for

registrants to provide information about

their indemnity arrangements?

3.	Do you agree with the proposed changes on applications for entry in the register? (see sections 7.5-7.9 of the consultation document) Yes No Don't know Do you have any further comments in response to question 3?	4	Do you agree with the proposed changes on applications for renewal of an entry in the register? (see sections 7.10-7.12 of the consultation document) Yes No Don't know Do you have any further comments in response to question 4?

5.	Do you agree with the proposed changes on applications for an annotation to an entry in the register? (see sections 7.13-7.14 of the consultation document)	6.	Do you agree with the proposed changes on applications for renewal of an annotation to an entry in the register? (see sections 7.15-7.16 of the consultation document)
	□ Yes□ No□ Don't know		☐ Yes☐ No☐ Don't know
	Do you have any further comments in response to question 5?		Do you have any further comments in response to question 6?

7.	Do you agree with the proposed changes on applications for restoration of an entry in the register? (see sections 7.17-7.19 of the consultation document)	8.	Do you agree with the proposed changes on applications for restoration of an annotation to an entry in the register? (see sections 7.20-7.21 of the consultation document)
	□ Yes		□ Yes
	□ No □ Don't know		□ No □ Don't know
	Do you have any further comments in		Do you have any further comments in
	response to question 7?		response to question 8?

9.	Do you agree with the proposed changes to fitness to practise proceedings in cases where it is alleged that a pharmacy professional does not have the knowledge of English necessary for safe and effective practice? (see sections 8.1-8.8 of the consultation document)	10. Do you have any other comments you wat to make?		
	□ Yes □ No □ Don't know			
	Do you have any further comments in response to question 9?			

September 2015

Equality monitoring

At the GPhC, we are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties.

We want to make sure everyone has an opportunity to respond to our consultation on proposed changes to rules. This equality monitoring form will provide us with useful information to check that this happens. You do not have to fill it in, and your answers here will not be linked to your consultation responses.

What is your ethnic group?			
Please tick one box			
White	□ Irich	Othor	
British	☐ Irish	☐ Other	
Black or Black British Caribbean	African	Other	
Mixed	_		
White and black Caribbean	White and black African		
☐ White and Asian	other mixed (please give	.	
Asian or Asian British	more information in the box	k below)	
Indian	☐ Pakistani		
☐ Bangladeshi	other Asian (please give		
	more information in the box	x below)	
Chinese or Chinese British	☐ Other ethnic group	,	
	(please give more information	in the box below)	
What is your age? Under 20	☐ 20 – 29 years	□ 30 – 39 years	
☐ 40 – 49 years	☐ 50 – 59 years	☐ 60 + years	
What is your gender?			
Please tick one box			
☐ male	☐ female	other	
What is your sexual orientati	ion?		
Please tick one box	_	_	_
heterosexual	☐ lesbian / gay	bisexual	\square other
What is your religion? Please tick one box			
None	Christian	Buddhist	Hindu
Jewish	Muslim	Sikh	
Other (please give more information)	ation in the box below)		
Do you consider that you have	ve a disability?		
Please tick one box			
Yes	□No		

September 2015

Appendix 1

STATUTORY INSTRUMENTS

2015 No.

HEALTHCARE AND ASSOCIATED PROFESSIONS

PHARMACY

The General Pharmaceutical Council (Amendment of Miscellaneous Provisions) Rules Order of Council 2015

Made	***
Laid before Parliament	***
Laid before the Scottish Parliament	***
Coming into force	***

At the Council Chamber, Whitehall, the *** day of ***

By the Lords of Her Majesty's Most Honourable Privy Council

The General Pharmaceutical Council(a) has made the General Pharmaceutical Council (Amendment of Miscellaneous Provisions) Rules 2015 which are set out in the Schedule to this Order, in exercise of the powers conferred by articles 23(1), 27(1), 32(4), (6) and (7), 37(3), 52(1) and (2), 55A(1) and (3), 57(3), 61(1)(b) and (3)(h) and 66(1) of, and paragraph 5(1)(a) of Schedule 1 to, the Pharmacy Order 2010(b).

In accordance with article 66(3) of that Order, the General Pharmaceutical Council has, in relation to rules under Parts 4, 6 and 7 of that Order, consulted such persons and organisations as it considered appropriate including the persons and organisations listed in sub-paragraphs (a) to (h) of article 66(3) of that Order(c).

By virtue of article 66(4) of that Order, such rules cannot come into force until approved by order of the Privy Council.

Citation and commencement

1. This Order may be cited as the General Pharmaceutical Council (Amendment of Miscellaneous Provisions) Rules Order of Council 2015 and comes into force on [date].

⁽a) The Council was established by article 4 of the Pharmacy Order 2010 (S.I. 2010/231) ("the Pharmacy Order").

⁽b) Article 32 was substituted by S.I. 2014/1887. Article 55A was inserted, and article 61(3)(h) was amended, by S.I. 2015/806. See article 3(1) of the Pharmacy Order for the definition of "prescribed" which is relevant to the powers being exercised in the making of the Rules set out in the Schedule to this Order.

⁽c) Article 66(3)(a) was amended by S.I. 2013/235.

Council Approval

2. Their Lordships, having taken the Rules contained in the Schedule into consideration, are pleased to and do approve them.

Signatory text

Name
Clerk of the Privy Council

SCHEDULE

Article 2

The General Pharmaceutical Council (Amendment of Miscellaneous Provisions) Rules 2015

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The General Pharmaceutical Council makes these Rules in exercise of the powers conferred by articles 23(1), 27(1), 32(4), (6) and (7), 37(3), 52(1) and (2), 55A(1) and (3), 57(3), 61(1)(b) and (3)(h) and 66(1) of, and paragraph 5(1)(a) of Schedule 1 to, the Pharmacy Order 2010.

In accordance with article 66(3) of that Order, the General Pharmaceutical Council has, in relation to rules under Parts 4, 6 and 7 of that Order, consulted such persons and organisations as it considered appropriate including the persons and organisations listed in sub-paragraphs (a) to (h) of article 66(3) of that Order.

PART 1

General

Citation, commencement and interpretation

- **1.**—(1) These Rules may be cited as the General Pharmaceutical Council (Amendment of Miscellaneous Provisions) Rules 2015 and come into force on [date].
 - (2) In these Rules—
 - "the Fitness to Practise Rules" means the General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010(a);
 - "the Registration Rules" means the General Pharmaceutical Council (Registration) Rules 2010(b);
 - "the Statutory Committees and their Advisers Rules" means the General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010(c).

PART 2

Amendment to the General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010

Amendment of rule 18B of the Statutory Committees and their Advisers Rules

- 2. In rule 18B of the Statutory Committees and their Advisers Rules (composition of Appeals Committee: further provision)(d), in paragraph (2)—
 - (a) omit "and" at the end of sub-paragraph (b); and
 - (b) after sub-paragraph (c) insert "and
 - (d) any member who has sat in a formation of the Fitness to Practise Committee that has given advice on, or made findings of fact in relation to, a particular matter does not sit in a formation of the Appeals Committee that hears an appeal in proceedings connected with that matter."

⁽a) Scheduled to S.I. 2010/1615.

⁽b) Scheduled to S.I. 2010/1617.

⁽c) Scheduled to S.I. 2010/1616.

⁽d) Rule 18B was inserted by S.I. 2012/3171.

PART 3

Amendments to the General Pharmaceutical Council (Registration) Rules 2010

New rule 8A of the Registration Rules

3. After rule 8 of the Registration Rules insert—

"Duty to provide information about indemnity arrangements: registrants

- **8A.**—(1) A registrant entered in Part 1 or, as the case may be, Part 2 of the Register must provide such information as the Registrar may require by notice in writing for the purposes of determining whether, at any time, there is in force an indemnity arrangement which provides appropriate cover in relation to the registrant or to registrants of a particular description(a).
- (2) Information which may be required by a notice under paragraph (1) includes, in particular—
 - (a) the name and address of any employer of the registrant;
 - (b) a description of the activities within the scope of the registrant's practice as a pharmacist or, as the case may be, a pharmacy technician;
 - (c) details of any insurance policy or other arrangement which provides appropriate cover in relation to the registrant which—
 - (i) was in force in respect of any period specified in the notice,
 - (ii) is in force when the notice is issued, or
 - (iii) will be in force by the time the registrant begins to practise as a pharmacist or, as the case may be, a pharmacy technician; and
 - (d) the name of any person or persons providing any such insurance policy or other arrangement.
- (3) The registrant must provide the information required by a notice under paragraph (1)—
 - (a) within the period of 7 days starting with the date on which the Registrar issues the notice; or
 - (b) if in all the circumstances it appears to the Council reasonable to do so, within such longer period as the Registrar may specify in the notice.
- (4) A notice under paragraph (1) must inform the registrant that, if the required information is not provided in accordance with the requirements of paragraph (3)—
 - (a) the Registrar may, under article 32(8) of the Order, refuse to renew the registrant's entry in Part 1 or 2 of the Register (as the case may be);
 - (b) the Registrar may, under article 32(9)(a) of the Order, remove the registrant's name from that part of the Register; or
 - (c) the registrant's failure to comply with those requirements may, by virtue of article 32(9)(b) of the Order, be treated as misconduct for the purposes of article 51(1)(a) of the Order.
- (5) A registrant entered in Part 1 or, as the case may be, Part 2 of the Register must in the event that there is in force no indemnity arrangement which provides appropriate cover in relation to the registrant, inform the Registrar in writing of that fact within 7 days of the cessation of appropriate cover under any such arrangement."

⁽a) "Indemnity arrangement" and "appropriate cover" are defined in article 32(2) and (3) of the Pharmacy Order.

Amendment of rule 10 of the Registration Rules

- **4.**—(1) Rule 10 of the Registration Rules (entry in the Register)(a) is amended as follows.
- (2) In paragraph (2)(a)(iii)—
 - (a) omit "and" at the end of sub-paragraph (bb); and
 - (b) after sub-paragraph (cc) insert—
 - "(dd) understands that, upon entry in the Register, the applicant cannot practise as a pharmacist or, as the case may be, a pharmacy technician unless there is in force an indemnity arrangement which provides appropriate cover in relation to the applicant, and
 - (ee) agrees, in the event that there is in force in relation to the applicant no such arrangement, to inform the Registrar in writing of that fact within 7 days of the cessation of appropriate cover under any such arrangement and understands that the applicant's entry may be removed from the Register,".
- (3) In paragraph (3)—
 - (a) in each of sub-paragraphs (a)(i), (c)(i), (d)(i) and (f)(ii), for "which meets the conditions set out in paragraph (3A)" substitute "to which paragraph (3A) applies";
 - (b) omit "and" at the end of sub-paragraph (j); and
 - (c) after sub-paragraph (k) insert "; and
 - (l) evidence, information or documents demonstrating that the applicant has the necessary knowledge of English for the purpose of complying with article 20(1)(a)(iia) of the Order(b).".
- (4) For paragraph (3A) substitute—
 - "(3A) This paragraph applies to a copy of—
 - (a) a United Kingdom passport within the meaning of the Immigration Act 1971(c) (whether or not the front cover of the passport is included in the copy); or
 - (b) any other passport,

which is certified by a notary, solicitor or Commissioner for Oaths as a true copy of an original passport referred to in sub-paragraph (a) or (b).".

- (5) After paragraph (3B) insert—
 - "(3C) Where an application under this rule is made by a person whose name was removed from the Register, or part of the Register, under article 32(9)(a) of the Order, the evidence to be provided under paragraph (3)(ga) is—
 - (a) a copy of any insurance policy or other arrangement indemnifying the applicant which is in force, or the details of any such policy or arrangement which will be in force, in relation to the applicant; and
 - (b) a description of the activities which the applicant intends to undertake when practising as a pharmacist or, as the case may be, a pharmacy technician.".
- (6) In paragraph (5)—
 - (a) for "The additional matters referred to in paragraph (4) are—" substitute "The following may, in particular, be required under paragraph (4)—"

⁽a) Rule 10(2)(a)(ii)(cc) and (3)(ga) were inserted by S.I. 2014/1887. Rule 10(3) and (5)(b) were amended, and rule 10(3A) and (3B) were inserted, by S.I. 2012/3171. Rule 10(5)(a), (e) and (f) and (12) were amended, and rule 10(5)(g) was inserted, by S.I. 2010/2660.

⁽b) A definition of "the necessary knowledge of English" was inserted in article 3(1) of the Pharmacy Order by S.I. 2015/806. In determining whether a person has the necessary knowledge of English, the Registrar is required to have regard to guidance published by the Council under article 23A of the Pharmacy Order. Article 23A was inserted by S.I. 2015/806.

⁽c) 1971 c. 77. The definition of "United Kingdom Passport" in section 33 of that Act was inserted by paragraph 7(a)(ii) of Schedule 4 to the British Nationality Act 1981 (c. 61) and amended by section 1(1)(b) of the British Overseas Territories Act 2002 (c. 8).

- (b) omit "and" at the end of sub-paragraph (f); and
- (c) at the end of sub-paragraph (g) insert "; and
 - (h) in the case of an applicant who provided the evidence referred to in paragraph (3)(ga) by way of a self-declaration—
 - (i) a copy of any insurance policy or other arrangement indemnifying the applicant which is in force, or the details of any such policy or arrangement which will be in force, in relation to the applicant; and
 - (ii) a description of the activities which the applicant intends to undertake when practising as a pharmacist or, as the case may be, a pharmacy technician.".

Amendment of rule 11 of the Registration Rules

- **5.**—(1) Rule 11 of the Registration Rules (renewal of an entry in the Register)(a) is amended as follows.
 - (2) In paragraph (4)(a)—
 - (a) in paragraph (iia), for "provide evidence that" substitute "specify whether";
 - (b) after that paragraph insert—
 - "(iib) declare that the registrant understands that the registrant cannot practise as a pharmacist or, as the case may be, a pharmacy technician unless there is in force an indemnity arrangement which provides appropriate cover in relation to the registrant,
 - (iic) declare that the registrant agrees, in the event that there is in force in relation to the registrant no such arrangement, to inform the Registrar in writing of that fact within 7 days of the cessation of appropriate cover under any such arrangement and understands that the registrant's entry may be removed from the Register, "; and
 - (c) omit "and" at the end of paragraph (iv); and
 - (d) after paragraph (v) insert ", and—
 - (vi) specify whether the registrant holds evidence, information or documents demonstrating that the registrant has the necessary knowledge of English for the purpose of complying with article 20(1)(a)(iia) of the Order;".
 - (3) After paragraph (5) insert—
 - "(5A) The registrant must also provide such additional documents, information or evidence as the Registrar may reasonably require for the purposes of verifying the information in, or determining, the application."
- (4) In paragraph (6)(b), after "as mentioned in the application form" insert "or subsequently required by the Registrar".

Amendment of rule 12 of the Registration Rules

- **6.**—(1) Rule 12 of the Registration Rules (annotations made to an entry in the Register) is amended as follows.
 - (2) In paragraph (3)(a)—
 - (a) omit "and" at the end of paragraph (v);
 - (b) after paragraph (v) insert—
 - "(va) specify whether, if an annotation in respect of a specialisation were to be made to the applicant's entry, there would be in force an indemnity

⁽a) Rule 11(4)(a)(iia) was inserted by S.I. 2014/1887.

- arrangement which provides appropriate cover in relation to the applicant, and"; and
- (c) in paragraph (vi), after "provide" insert "any necessary supporting documents specified in paragraph (3A) and".
- (3) After paragraph (3) insert—
 - "(3A) Where an application under this rule is made by a person whose name was removed from the Register, or part of the Register, under article 32(9)(a) of the Order, the applicant must provide to the Registrar, together with the applicant's application form—
 - (a) a copy of any insurance policy or other arrangement indemnifying the applicant which is in force, or the details of any such policy or arrangement which will be in force, in relation to the applicant; and
 - (b) a description of the activities which the applicant intends to undertake when practising as a pharmacist or, as the case may be, a pharmacy technician.".

Amendment of rule 13 of the Registration Rules

- 7.—(1) Rule 13 of the Registration Rules (renewal of an annotation made to an entry in the Register) is amended as follows.
 - (2) In paragraph (4)(b), after paragraph (iii) insert—
 - "(iiia) specify whether, if an annotation in respect of a specialisation were to be renewed, there would be in force an indemnity arrangement which provides appropriate cover in relation to the applicant,".
- (3) In paragraph (6)(b), after "as mentioned in the application form" insert "or subsequently required by the Registrar".

Amendment of rule 16 of the Registration Rules

- **8.**—(1) Rule 16 of the Registration Rules (restoration of an entry in the Register) is amended as follows.
 - (2) In paragraph (3)(a)—
 - (a) omit "and" at the end of paragraph (ii)(bb);
 - (b) after paragraph (ii)(cc) insert—
 - "(dd) that A understands that, upon A's entry being restored to the Register, A cannot practise as a pharmacist or, as the case may be, a pharmacy technician unless there is in force an indemnity arrangement which provides appropriate cover in relation to A, and
 - (ee) that A agrees, in the event that there is in force in relation to A no such arrangement, to inform the Registrar in writing of that fact within 7 days of the cessation of appropriate cover under any such arrangement and understands that A's entry may be removed from the Register,";
 - (c) in paragraph (iii)—
 - (i) in each of sub-paragraphs (aa) and (bb), for "the registrant" substitute "A";
 - (ii) in sub-paragraph (bb), for "the registrant's" substitute "A's"; and
 - (iii) omit "and" at the end of sub-paragraph (bb);
 - (d) after paragraph (iii) insert—
 - "(iiia) specify whether A holds evidence, information or documents demonstrating that A has the necessary knowledge of English for the purpose of complying with article 20(1)(a)(iia) of the Order, and"; and
 - (e) in paragraph (iv), for "provide any" substitute "provide any necessary supporting documents specified in paragraph (3A) and any other".

- (3) After paragraph (3) insert—
 - "(3A) Where an application under this rule is made by a person whose name was removed from the Register, or part of the Register, under article 32(9)(a) of the Order, the applicant must provide to the Registrar, together with the applicant's application form—
 - (a) a copy of any insurance policy or other arrangement indemnifying the applicant which is in force, or the details of any such policy or arrangement which will be in force, in relation to the applicant; and
 - (b) a description of the activities which the applicant intends to undertake when practising as a pharmacist or, as the case may be, a pharmacy technician.".

Amendment of rule 17 of the Registration Rules

- **9.**—(1) Rule 17 of the Registration Rules (restoration of an annotation made to an entry in the Register) is amended as follows.
 - (2) In paragraph (3)(a)—
 - (a) in paragraph (i), after sub-paragraph (aa) insert—
 - "(ab) whether, if an annotation in respect of a specialisation were to be restored to the applicant's entry, there would be in force an indemnity arrangement which provides appropriate cover in relation to the applicant,"; and
 - (b) in paragraph (ii), after "provide" insert "any necessary supporting documents specified in paragraph (3A) and".
 - (3) After paragraph (3) insert—
 - "(3A) Where an application under this rule is made by a person whose name was removed from the Register, or part of the Register, under article 32(9)(a) of the Order, the applicant must provide to the Registrar, together with the applicant's application form—
 - (a) a copy of any insurance policy or other arrangement indemnifying the applicant which is in force, or the details of any such policy or arrangement which will be in force, in relation to the applicant; and
 - (b) a description of the activities which the applicant intends to undertake when practising as a pharmacist or, as the case may be, a pharmacy technician.".

PART 4

Amendments to the General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010

Amendment of rule 2 of the Fitness to Practise Rules

10. In rule 2 of the Fitness to Practise Rules (interpretation), in paragraph (1), after the definition of "interim order hearing" insert—

"knowledge of English allegation" means a complaint to, or concern of, the Council which gives rise to, or may give rise to, an inquiry that a person's fitness to practise is impaired by reason of article 51(1)(ca) of the Order(a);".

Amendment of rule 6 of the Fitness to Practise Rules

11.—(1) Rule 6 of the Fitness to Practise Rules (initial action in respect of allegations) is amended as follows.

⁽a) Article 51(1)(ca) was inserted by S.I. 2015/806.

- (2) In paragraph (4)—
 - (a) omit "or" at the end of sub-paragraph (c); and
 - (b) after sub-paragraph (d) insert "; or
 - "(e) in relation to a knowledge of English allegation, directing the person concerned—
 - (i) to undertake an examination or other assessment of that person's knowledge of English, and
 - (ii) to provide to the Registrar evidence of the result of that examination or assessment.".
- (3) After paragraph (4) insert—
 - "(4A) Any direction under paragraph (4)(e) is to be given by the Registrar by a notice in writing which—
 - (a) specifies the name of the examination or assessment of knowledge of English which the person concerned is required to undertake;
 - (b) states that the evidence referred to in paragraph (4)(e)(ii) is to be provided in the form of a certificate or other document which—
 - (i) states the result of the examination or assessment, and
 - (ii) is signed by an officer of the body which provides the examination or assessment; and
 - (c) specifies the date by which such evidence is to be provided,

and the person concerned must comply with the direction by the date specified in the notice or, if the Registrar agrees by a further notice in writing to extend that period, within the extended period specified in that notice.

- (4B) The Registrar may disclose to any of the statutory committees or any employee of the Council any evidence provided pursuant to a direction given under paragraph (4)(e).".
- (4) After paragraph (7A)(a) insert—
 - "(7B) Where the Registrar has given a direction under paragraph (4)(e) and the person concerned has failed to comply with it, the Registrar may—
 - (a) refer the knowledge of English allegation to the Committee instead of to the Investigating Committee and treat the failure to comply with the direction as a separate allegation of misconduct and refer that allegation to the Committee; or
 - (b) determine not to refer the knowledge of English allegation to the Committee but treat the failure to comply with the direction as a separate allegation of misconduct and refer that allegation to the Committee.".
- (5) In paragraph (8), for "paragraph (5), (6), (7) or (7A)" substitute "any of paragraphs (5) to (7B)".

Amendment of rule 7 of the Fitness to Practise Rules

- **12.**—(1) Rule 7 of the Fitness to Practise Rules (notices of referral and documents to be supplied to persons concerned) is amended as follows.
 - (2) In paragraph (1)(b)—
 - (a) omit "and" at the end of paragraph (i); and
 - (b) after paragraph (ii) insert "; and
 - "(iii) where the person is the subject of a knowledge of English allegation, a copy of the guidance published by the Council under article 23A of the Order(b).".
 - (3) In paragraph (2), after sub-paragraph (d)(ii) insert—

⁽a) Paragraph (7A) was inserted by S.I. 2011/1367.

⁽b) Article 23A was inserted by S.I. 2015/806.

"(iia) in relation to a knowledge of English allegation, to direct the person concerned to undertake an examination or other assessment of that person's knowledge of English,".

Amendment of rule 8 of the Fitness to Practise Rules

- 13.—(1) Rule 8 of the Fitness to Practise Rules (applications for restoration) is amended as follows.
 - (2) In paragraph (3)(b), after paragraph (i) insert—
 - "(ia) evidence, information or documents demonstrating that the person has the necessary knowledge of English for the purpose of complying with article 20(1)(a)(iia) of the Order;".
 - (3) After paragraph (4) insert—
 - "(4A) If, having considered any evidence, information or documents provided under paragraph (3)(b)(ia), the Registrar is not satisfied that the person applying for restoration to Part 1 or, as the case may be, Part 2 of the Register has the necessary knowledge of English, the Registrar may direct the person—
 - (a) to undertake an examination or other assessment of that person's knowledge of English, and
 - (b) to provide to the Registrar evidence of the result of that examination or assessment.
 - (4B) Any direction under paragraph (4A) is to be given by the Registrar by a notice in writing which—
 - (a) specifies the name of the examination or assessment of knowledge of English which the person is required to undertake;
 - (b) states that the evidence referred to in paragraph (4A)(b) is to be provided in the form of a certificate or other document which—
 - (i) states the result of the examination or assessment; and
 - (ii) is signed by an officer of the body which provides the examination or assessment; and
 - (c) specifies the date by which such evidence is to be provided,

and the person must comply with the direction by the date specified in the notice or, if the Registrar agrees by a further notice in writing to extend that period, within the extended period specified in that notice.

(4C) The Registrar may disclose to any of the statutory committees or any employee of the Council any evidence provided pursuant to a direction under paragraph (4A).".

Amendment of rule 9 of the Fitness to Practise Rules

- **14.** In rule 9 of the Fitness to Practise Rules (procedures of the Investigating Committee), after paragraph (5) insert—
 - "(5A) In relation to a knowledge of English allegation, the Investigating Committee may—
 - (a) give a direction in accordance with paragraph (5B) which requires the person concerned—
 - (i) to undertake an examination or other assessment of that person's knowledge of English, and
 - (ii) to provide to the Registrar evidence of the result of that examination or assessment; and
 - (b) where it receives information that the person concerned has failed to comply with any such direction—

- (i) refer the knowledge of English allegation to the Committee and treat the failure to comply with the direction as a separate allegation of misconduct and refer that allegation to the Committee; or
- (ii) determine not to refer the knowledge of English allegation to the Committee but treat the failure to comply with the direction as a separate allegation of misconduct and refer that allegation to the Committee.
- (5B) Any direction under paragraph (5A)(a) is to be given by the Investigating Committee by a notice in writing which—
 - (a) specifies the name of the examination or assessment of knowledge of English which the person concerned is required to undertake;
 - (b) states that the evidence referred to in paragraph (5A)(a)(ii) is to be provided in the form of a certificate or other document which—
 - (i) states the result of the examination or assessment; and
 - (ii) is signed by an officer of the body which provides the examination or assessment; and
 - (c) specifies the date by which such evidence is to be provided,

and the person concerned must comply with the direction by the date specified in the notice or, if the Registrar agrees by a further notice in writing to extend that period, within the extended period specified in that notice.

(5C) The Investigating Committee may disclose to any other statutory committee or any employee of the Council any evidence provided pursuant to a direction given under paragraph (5A)(a).".

Amendment of rule 13 of the Fitness to Practise Rules

- 15.—(1) Rule 13 of the Fitness to Practise Rules (action upon referral of an allegation) is amended as follows.
 - (2) In paragraph (1), after sub-paragraph (a) insert—
 - "(ab) in the case of a knowledge of English allegation, the chair may give a direction requiring the person concerned—
 - (i) to undertake an examination or other assessment of that person's knowledge of English, and
 - (ii) to provide to the Registrar evidence of the result of that examination or assessment;".
 - (3) After paragraph (1) insert—
 - "(1A) Any direction under paragraph (1)(ab) is to be given by the chair by a notice in writing which—
 - (a) specifies the name of the examination or assessment of knowledge of English which the person concerned is required to undertake;
 - (b) states that the evidence referred to in paragraph (1)(ab)(ii) is to be provided in the form of a certificate or other document which—
 - (i) states the result of the examination or assessment; and
 - (ii) is signed by an officer of the body which provides the examination or assessment; and
 - (c) specifies the date by which such evidence is to be provided,

and the person concerned must comply with the direction by the date specified in the notice or, if the Registrar agrees by a further notice in writing to extend that period, within the extended period specified in that notice.

(1B) The Committee may disclose to any other statutory committee or any employee of the Council any evidence provided pursuant to a direction given under paragraph (1)(ab).".

Amendment of rule 24 of the Fitness to Practise Rules

- **16.** In rule 24 of the Fitness to Practise Rules (evidence), after paragraph (11) insert—
 - "(11A) In determining whether a person's fitness to practise is impaired by reason of not having the necessary knowledge of English, the Committee may take into account, amongst other matters—
 - (a) a failure by the person concerned to comply with a direction given under these Rules to undertake an examination or other assessment of that person's knowledge of English; and
 - (b) a failure by the person concerned to provide to the Registrar evidence of the result of any such examination or assessment.".

EXPLANATORY NOTE

(This note is not part of the Order)

This Order approves the General Pharmaceutical Council (Amendment of Miscellaneous Provisions) Rules 2015 ("the Rules"). The Rules were made by the General Pharmaceutical Council ("the Council") under the Pharmacy Order 2010 (S.I. 2010/231) ("the Pharmacy Order").

Part 2 of the Rules contains an amendment to the General Pharmaceutical Council (Statutory Committees and their Advisers) Rules 2010. The amendment in rule 2 prevents any person who has sat as a member of the Council's Fitness to Practise Committee when considering any matter from also acting as a member of the Appeals Committee in proceedings connected with the same matter.

Part 3 of the Rules amends provisions of the General Pharmaceutical Council (Registration) Rules 2010 ("the Registration Rules"). Rule 3 requires persons who are entered in Part 1 or Part 2 of the Register that is established and maintained under article 19 of the Order to provide to the Registrar information about any indemnity arrangement which relates to the person's practice as a registered pharmacist or a registered pharmacy technician. In rule 4, paragraphs (2), (5) and (6) impose requirements relating to the indemnity cover which an applicant for entry in Part 1 or 2 of the Register must have in place in order to practise as a pharmacist or pharmacy technician. Paragraphs (3)(b) and (c) of that rule require such applicants to demonstrate that they have the knowledge of English necessary to practise as a pharmacist or pharmacy technician. The remaining provisions of rule 4 provide that a copy of a UK passport, which is required when making an application for registration, does not need to include the front cover. Rule 5 requires registrants who are making an application to renew their registration to meet specified requirements relating to indemnity cover and knowledge of English. Rule 6 imposes requirements about indemnity cover in relation to registrants applying to have an annotation in respect of a specialisation made to their entry in Part 1 or 2 of the Register and rule 7 imposes requirements about indemnity cover in relation to registrants making an application to renew any such annotation. Rule 8 imposes requirements about indemnity cover and knowledge of English in relation to applicants for the restoration of an entry in Part 1 or 2 of the Register. Rule 9 imposes requirements about indemnity cover in relation to applicants for the restoration of an annotation to such an entry.

Part 4 of the Rules makes a number of amendments to the General Pharmaceutical Council (Fitness to Practise and Disqualification etc.) Rules 2010. Rule 10 defines what is meant by "a knowledge of English allegation". Rule 11 enables the Registrar to give a direction requiring a person subject to such an allegation to undertake an examination or other assessment as to their knowledge of English and to provide the Registrar with the results obtained. Rule 11 also enables any failure to comply with such a direction to be referred directly to the Council's Fitness to Practise Committee instead of to its Investigating Committee. Rule 12 makes provision as to information that must be provided to any person subject to a knowledge of English allegation that has been referred to the Investigating Committee. In the case of a person applying for restoration of an entry which was removed from the Register by a direction given by the Fitness to Practise Committee, rule 13 provides that the evidence which the person must provide to demonstrate that they are fit to return to practice may include evidence that the person has the knowledge of

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English necessary to practise as a pharmacist or pharmacy technician. It also enables the Registrar to require any such applicant to undertake an examination or other assessment as to their knowledge of English and to provide the Registrar with the results obtained. Rule 14 enables the Investigating Committee to require a person subject to a knowledge of English allegation to undertake an examination or other assessment as to their knowledge of English and to provide the Registrar with the results obtained and rule 15 confers equivalent powers on the Fitness to Practise Committee. Rule 16 enables the Fitness to Practise Committee to take account of a person's failure to comply with a direction requiring the person to undertake a knowledge of English assessment when that Committee is determining whether a person's fitness to practise is impaired.

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