

Consultation report: 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**

August 2016

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Consultation report on amendments to rules

Summary

1. The General Pharmaceutical Council ('GPhC') is the independent regulator for pharmacists, pharmacy technicians and registered pharmacies in Great Britain.
2. In late 2015, we consulted on changes to some of our rules. The main purpose of these proposals was 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. We consulted on amendments to the following rules:

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)

3. This report provides a summary of the responses to the consultation and a commentary in relation to our proposals.
4. The responses we received were broadly supportive, and we have decided to go ahead with the proposed changes.
5. We are grateful for the feedback we have received. We will continue to keep the content of our rules under review.
6. Alongside the consultation on amendments to rules, we consulted on draft guidance about the evidence, information and documents that may be provided by an applicant or registrant for the purpose of satisfying the registrar that they have the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 consultation can be found at www.pharmacyregulation.org/previous-consultations

1. Background

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

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

Our core functions include:

- setting the standards of education and training which pharmacists and pharmacy technicians must meet in order to join our register and remain registered throughout their professional life
- registering pharmacists and pharmacy technicians and setting the standards of conduct and performance which they must meet to stay on our register
- setting standards for the safe and effective practice of pharmacy at registered pharmacies
- registering pharmacies which meet those standards and inspecting them to check that they continue to do so
- taking action when our standards are not met, typically through fitness to practise proceedings and enforcement action

We aim to make sure that regulation is fair and proportionate – taking into account the risk posed to public health, safety and wellbeing – and not over-burdensome. We want it to be flexible enough to respond to the changing demands made of the profession by governments on behalf of the public, and allow for innovation, while at the same time maintaining high quality practice.

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’.

We consulted on proposed amendments to the following rules:

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).

The main purpose of these proposals was 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.

Further information about the work of the GPhC can be found on our website at www.pharmacyregulation.org

About this report

This report provides a summary of the responses to the consultation on draft amendments to rules held between 24 September and 17 December 2015.

The report provides background to the consultation, a breakdown of the responses to our proposals and a commentary on the responses. We recommend that the statistical information on the responses is read in conjunction with the commentary. Appendix 1 provides a list of organisations that responded to the consultation.

Responses to the consultation

We received 73 responses to the consultation. In analysing the responses, we have calculated percentages to 0.1 of a decimal point, which means that the total may be fractionally more or less than a hundred in some cases.

Respondents by type		
Individual	33	45.2%
Organisation	9	12.3%
Skipped question	31	42.4%
Total	73	100%

Individual type		
A pharmacy professional	27	37.0%
A member of the public	5	6.8%
Other	0	0.0%
Skipped question	41	56.1%
Total	73	100%

Pharmacy professional type		
Pharmacist	23	31.5%
Pharmacy technician	3	4.1%
Skipped question	47	64.4%
Total	73	100%

Respondents by country		
England	22	30.1%
Scotland	1	1.4%
Wales	2	2.7%
Northern Ireland	0	0.0%
Other	3	4.1%
Skipped question	45	61.7%
Total	73	100%

Areas worked in		
Community pharmacy	11	15.1%
Hospital pharmacy	6	8.2%

Primary care organisation	0	0.0%
Pharmacy education and training	8	11.0%
Pharmaceutical industry	0	0.0%
Other	2	2.7%
Skipped question	46	63.0%
Total	73	100%

Respondents working in community pharmacy		
Pharmacy owner	1	1.4%
Employee	11	15.1%
Self-employed locum	3	4.1%
Skipped question	58	79.5%
Total	73	100%

Organisation type		
Pharmacy organisation	6	8.2%
Non-pharmacy organisation	2	2.7%
Skipped question	65	89.0%
Total	73	100%

2. Indemnity arrangements

- 2.1 The Health Care and Associated Professions (Indemnity Arrangements) Order 2014 ('Indemnity Arrangements Order') amended the Pharmacy Order 2010 so as to implement a requirement across health professions 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 systems of professional liability cover or similar in place in respect of cross-border healthcare for patients receiving treatment in their member state.
- 2.2 The requirement for pharmacists and pharmacy technicians to have indemnity cover is not new. Registrants were already under an obligation, under article 32 of the Pharmacy Order, to have appropriate indemnity cover in force.
- 2.3 Article 32 of the Pharmacy Order sets out that an indemnity arrangement may be: an insurance policy; an arrangement made for the purposes of indemnifying a person, for example by an employer, or a combination of the two. 'Appropriate cover' means 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). Article 32 also enables the GPhC to make rules concerning the information to be provided to the registrar for the purposes of determining whether there is, or will be, an indemnity arrangement in force which provides appropriate cover in relation to that person.
- 2.4 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.
- 2.5 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.

3. Knowledge of English

- 3.1 The Health Care and Associated Professions (Knowledge of English) Order 2015 ('Knowledge of English Order') amends the Pharmacy Order to strengthen the GPhC's

powers by introducing 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.

- 3.2 The Knowledge of English Order requires the GPhC to consult on and publish guidance setting out the evidence, information or documents that an applicant 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. We consulted on this draft guidance alongside the consultation on changes to our rules. The consultation report on the guidance can be found here <http://www.pharmacyregulation.org/previous-consultations>.
- 3.3 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.
- 3.4 The Knowledge of English Order creates a new category of impairment of fitness to practise relating to competence in the English language. 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.

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

- 4.1 This section covers amendments to 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

What we proposed

- 4.2 We proposed amending the rules to avoid conflicts of interest arising from common membership of Appeals Committee and Fitness to Practise Committee panels.
- 4.3 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 can also consider 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.

- 4.4 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 proposed amending the rules to prevent this happening.
- 4.5 There are a few situations where the Appeals Committee and the FtPC could be considering the same issues:
- The Appeals Committee may request advice from the FtPC under rule 9(1)(d) of the Appeals Committee Rules (S.I.2010/1614)
 - 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)
 - The registrar may determine that a registrant's entry in the register has been fraudulently procured or incorrectly made (art 29(3), Pharmacy Order) and remove the entry accordingly. 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)

What we heard

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?		
Yes	62	85.0%
No	3	4.1%
Don't know	8	11.0%
Skipped question	0	0.0%
Total	73	100%

- 4.6 85% of respondents agreed with this proposal and 4.1% disagreed. 11% of respondents stated that they did not know.
- 4.7 Comments made included that this change would strengthen the credibility of the committees' decisions and would be appropriate to ensure a transparent process and make any appeal independent of the original decision-making body.
- 4.8 One comment indicated that this would depend on the situation and the particular conflict of interest. Another said that where a member had not been involved previously, they should be allowed to sit. The proposed change would allow a member who had not been involved previously to sit on an Appeals Committee panel. However, where a member had sat on a Fitness to Practise Committee panel that had given advice on, or made findings of fact in relation to, a particular matter, they would not be able to sit on an Appeals Committee panel in connection with that matter.

Our response

- 4.9 We propose to go ahead and amend the Statutory Committees and their Advisers Rules to prevent common membership of Fitness to Practise Committee and Appeals Committee panels where this could give rise to a potential conflict of interest.

5. Amendments to the GPhC Registration Rules

- 5.1 This section covers amendments to The General Pharmaceutical Council (Registration) Rules 2010 (S.I. 2010/1617). Most of the changes we proposed were 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.

Duty to provide information about indemnity arrangements: registrants

What we proposed

- 5.2 We proposed inserting 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. The information would need to be provided within seven days of the date of the notice but that period could be longer if that was reasonable in the circumstances. 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. All registrants would have to inform the registrar within seven days if they ceased to have an appropriate indemnity arrangement in force.

What we heard

Question 2 - Do you agree with the proposed duty for registrants to provide information about their indemnity arrangements?		
Yes	36	49.3%
No	18	24.7%
Don't know	10	13.7%
Skipped question	9	12.3%
Total	73	100%

- 5.3 49.3% of respondents agreed with this proposal and 24.7% disagreed. 26% of respondents chose not to respond to this question or stated that they did not know.
- 5.4 Some respondents suggested that not all registrants needed an indemnity arrangement as their employer provided indemnity cover for them. Another requested guidance on this point. Others suggested that some registrants, such as those working in academia or government, may not require indemnity cover because of the nature of their work. Another sought guidance on the requirements for a registrant who was practising overseas.
- 5.5 Two pharmacy organisations raised concerns about the potential need for a registrant to provide information about their indemnity arrangements within seven days, if required. One expressed concern that an NHS employee may be unable to obtain evidence of indemnity cover from their employer within seven days, and asked whether an NHS job description would be sufficient evidence, on the basis that the employer's vicarious liability should be sufficient for a pharmacy professional employed by an NHS body and undertaking the duties detailed in their job description. Another organisation queried a registrant's ability to meet a seven-day deadline if, for

example, they were on holiday. This organisation also suggested that, if a request for evidence of indemnity cover was made together with the annual renewal notice, this would effectively mean that the registrant would need to apply for renewal within seven days, which could raise cash flow issues for contractors.

- 5.6 A pharmacy organisation queried whether each employed registrant would need to submit a copy of their employer's indemnity cover, and commented that there was no indication of how frequently this would be requested.
- 5.7 The same organisation asked whether, if a registrant left an employer and took a period of unpaid leave before starting another job, they would need to inform the registrar that they did not have indemnity cover during this period and could potentially be removed from the register. They believed that this depended upon the definition of 'practising' and asked that this be set out, querying whether a registrant should refuse a friend's request for advice during a period when they were between employers and did not have indemnity cover.
- 5.8 Another pharmacy organisation expressed support for the GPhC's duty to implement statutory requirements in relation to indemnity arrangements and knowledge of English. It was keen to avoid ambiguity in the requirements and to ensure they could be met using existing systems and processes, so that they would not be over-burdensome. They sought clarification:
- that registrants would not be routinely required to produce evidence of indemnity arrangements within seven days as part of the annual renewal process
 - that at the time of renewal, registrants would be required to specify whether they have, or will have, appropriate indemnity arrangements in place, and that they have evidence, information or documents demonstrating the necessary knowledge of English, using a self-declaration
 - on the circumstances in which registrants may be removed from the register if appropriate indemnity cover is not in place, to avoid a situation where a registrant may be removed from the register simply because they are not currently practising and therefore may not have indemnity arrangements in place
- 5.9 Another pharmacy organisation supported the proposals, considering them to be necessary as proposed.
- 5.10 One respondent asked about evidence to show that imposing indemnity requirements on registrants would have an impact on patient safety.
- 5.11 Another pharmacy organisation, whilst not opposing the majority of the proposals, raised some questions and concerns:
- whether registrants and indemnity providers would need to retain historical proof of indemnity cover indefinitely, in case it was requested by the registrar

- whether a registrant would be able to have sight of their employer’s professional indemnity insurance certificate and policy, in order to satisfy themselves as to whether their employer’s cover was sufficient for them. They recommended that employers be required to provide employees with sight of their professional indemnity insurance certificate
- the potential for cover under an employer’s professional indemnity policy to be conditional on whether the employee had followed the employer’s legal or other advice, or whether the employer had identified a performance issue with the employee
- whether particular types of indemnity arrangements would provide appropriate cover for registrants

5.12 An arrangement or factor mentioned as potentially affecting the appropriateness of a particular indemnity arrangement for a registrant was Contingent Medical Malpractice cover, which relies on an employer having primary medical malpractice insurance and primary public liability cover in place, with the Contingent Medical Malpractice cover coming into operation if the employer’s primary cover fails. Also mentioned was an arrangement whereby an employer agrees with a professional indemnity insurance provider to settle claims up to a certain value. The organisation recommended that guidance be provided to registrants and employers about the suitability and minimum acceptable specification of indemnity insurance cover.

Our response

5.13 Registrants are already obliged, under the Pharmacy Order and the GPhC’s standards, to have appropriate indemnity arrangements in place. The proposed amendments to rules would set out in more detail the information that applicants or registrants may need to provide and the action that may be taken if a registrant does not comply with the indemnity requirements. The majority of registrants would simply confirm that they continue to meet the requirements for both indemnity arrangements and knowledge of English, by making a self-declaration when renewing their registration.

5.14 The rules would allow the registrar to issue a notice requiring a registrant to provide information about their indemnity arrangements. The period within which the information must be provided would be stated in the notice but would not be less than seven days. We propose to adjust the wording of the rules to make clear that seven days would be a minimum period – not a standard deadline. The minimum period of seven days was chosen on the basis that we may need to act promptly to protect the public, for example if concerns were raised that someone was practising without indemnity cover and patients could be at risk. This would also be in line with the seven day period within which registrants must inform the registrar of any specified event that may affect their fitness to practise, such as convictions or cautions (rule 4, Fitness to Practise and Disqualification etc Rules). We intend to take a proportionate and risk-based approach, using this minimum period only when we consider it necessary for public protection.

- 5.15 We would not request evidence of indemnity cover from registrants on a routine basis but we may seek such evidence on occasion, for example when a complaint has been made or when there are concerns that appropriate cover may not be in place. There would be no requirement to provide evidence of indemnity cover as part of the standard renewal process. The renewal process would require a self-declaration. If it happened that we needed to seek evidence of indemnity cover from a registrant during their renewal period (for example, because concerns had been raised that they did not have cover in place), the notice requesting this information would be sent separately from the renewal notice and would state the deadline for providing this information.
- 5.16 It would be the responsibility of an individual registrant to provide information about their indemnity cover if required, not their employer. However, it would not be necessary for every employed registrant to submit a copy of their employer's indemnity cover – this would only need to be provided by an individual registrant on request.
- 5.17 The rules would also allow the registrar to require registrants to provide evidence of indemnity cover from past periods. Again, we intend to take a reasonable and proportionate approach to making such requests. We would not expect registrants to retain evidence of indemnity cover from past periods indefinitely but we would expect a registrant to seek such evidence from the relevant employer or indemnity provider if requested. If the relevant indemnity provider had destroyed all such evidence under their records retention policy, before the request was made, the registrant would need to inform us accordingly.
- 5.18 Practising as a pharmacist or pharmacy technician is defined in the Pharmacy Order 2010 (article 3(2)) as being when 'acting in the capacity of or purporting to be a pharmacist or pharmacy technician, that person undertakes any work or gives any advice in relation to the preparation, assembly, dispensing, sale, supply or use of medicines, the science of medicines, the practice of pharmacy or the provision of healthcare'.
- 5.19 It is each registrant's responsibility to ensure that they have appropriate indemnity arrangements for all aspects of their practice. Given the range of pharmacy practice, we do not propose to offer guidance about what would be considered adequate scope and funding of indemnity cover. These are both aspects that registrants must consider. If they are unsure, they should check with their employer or indemnity provider.
- 5.20 As is the case under the existing requirements, being covered by an employer's indemnity arrangements would not exempt a registrant from the requirement to have appropriate indemnity cover but it could mean that a registrant did not need to purchase additional cover. If a registrant's employer had indemnity arrangements which provided appropriate cover in respect of liabilities that may be incurred in

relation to that registrant's practice, the registrant could simply provide details of their employer's indemnity arrangements when requested.

- 5.21 An employed registrant, whether they work for a pharmacy owner or another employer, should consider whether any indemnity or insurance cover provided by their employer is sufficient or whether they need to make any additional arrangements to ensure appropriate cover for all aspects of their practice.
- 5.22 If a registrant was not practising at all for a period, for example because they were on a career break, maternity leave or between jobs, we would not require them to have indemnity cover during this period, although they might need run-off cover for any claims made relating to their previous time in practice. They would need to inform us within seven days of their indemnity cover ceasing and ensure that they had appropriate indemnity arrangements in place before beginning to practise again.
- 5.23 In relation to the impact of the changes on patient safety, this was considered in the impact assessment for the Health Care and Associated Professions (Indemnity Arrangements) Order 2014. This stated that some regulated health professionals were practising without indemnity or insurance cover, or with insufficient cover. The full benefits of the new arrangements would accrue to patients, who bear the cost of adverse events both in terms of cost and personal impact. They would have access to redress for any harm caused by the negligent activities of health care professionals. In addition, health care professionals who are covered by an appropriate indemnity arrangement, should they be involved in a negligent act that causes harm, would not be in danger of losing personal assets and potentially being made bankrupt.
- 5.24 The responses we received were broadly supportive, and we intend to go ahead with the proposals, with an adjustment to make clear that seven days would be the minimum period for responding to a request for information on indemnity arrangements – not a standard deadline. However, we recognise that there is a need for further guidance on indemnity arrangements. We will produce and publish guidance covering topics such as: employed and self-employed registrants, registrants in non-clinical practice, registrants practising overseas, registrants who are not currently practising and Good Samaritan acts, amongst others.

Entry in the register

What we proposed

Indemnity arrangements

- 5.25 We proposed amending 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

5.26 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. An applicant who completed a self-declaration would also need to supply additional evidence if requested by the registrar, as described above.

Crown copyright and the front cover of a UK passport

5.27 In 2012, the Registration Rules were amended so 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.

5.28 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 proposed amending the rules so that a certified copy of a UK passport may or may not include the front cover.

Knowledge of English

5.29 An applicant for registration would also be required to provide evidence of having the necessary knowledge of English. 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 of the Pharmacy Order, which was inserted by the Knowledge of English Order and came into force on 1 June 2016). The consultation on this guidance ran alongside the consultation on amendments to rules and the report can be found here <http://www.pharmacyregulation.org/previous-consultations>.

What we heard

Question 3 - Do you agree with the proposed changes on applications for entry in the register?		
Yes	36	49.3%
No	10	13.7%
Don't know	10	13.7%
Skipped question	17	23.3%
Total	73	100%

- 5.30 49.3% of respondents agreed with this proposal and 13.7% disagreed. 37% of respondents chose not to respond to this question or stated that they did not know.
- 5.31 One respondent indicated that not all registrants would need to have evidence of the necessary knowledge of English but did not specify why this was. Another suggested that all non-UK applicants should be required to achieve a score of at least 7 in each of the four areas of reading, writing, listening and speaking in the International English Language Testing System (IELTS) test.

Our response

- 5.32 We propose to go ahead with the amendments, subject to some minor amendments to the indemnity provisions made upon advice from Privy Council advisers. The amendments remove the express provisions requiring an applicant who has been removed from the register previously for failing to comply with the indemnity requirements 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. Instead of an express provision, we will simply request that additional evidence from all such applicants under the Registrar's power to do so. This avoids unnecessary duplication of information-gathering powers.
- 5.33 All registrants and applicants would need to be able to provide evidence of having the necessary knowledge of English on request. However, as set out in the draft guidance on evidence of language skills, this could be done in a number of ways, depending upon the background of the applicant or registrant. For example, our draft guidance proposed that UK qualified pharmacy professionals who have:

- successfully completed the relevant approved qualifications taught and examined in English under the supervision of a registered pharmacist in line with our registration criteria, and
- provided documentary evidence of these qualifications with their application for registration

would not normally be required to provide additional evidence to satisfy the registrar that they have the necessary knowledge of English.

- 5.34 The draft guidance also proposed that non-UK qualified applicants could provide different types of evidence to demonstrate their knowledge of English, including: evidence of having been awarded a primary pharmacy qualification taught and examined solely in English in a country where English is the first and native language; evidence of recent practice of at least two years in a country where English is the first and native language, or evidence of having achieved the required scores in the IELTS test.
- 5.35 We believe that having a range of acceptable types of evidence of knowledge of English, depending upon the background of the applicant or registrant, should allow a proportionate approach whilst providing the registrar with adequate assurance that the person has the necessary knowledge of English for the safe and effective practice of pharmacy.

Renewal of an entry in the register

What we proposed

- 5.36 We proposed that an applicant for renewal would have to specify whether they had, or would have, an indemnity arrangement in force providing appropriate cover. They would also have to declare that they understood 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
- 5.37 An applicant for renewal would have to specify whether they hold evidence demonstrating that they have the necessary knowledge of English.
- 5.38 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.

What we heard

Question 4 - Do you agree with the proposed changes on applications for renewal of an entry in the register?		
Yes	31	42.5%
No	11	15.1%
Don't know	10	13.7%
Skipped question	21	28.8%
Total	73	100%

5.39 42.5% of respondents agreed with this proposal and 15.1% disagreed. 42.5% of respondents chose not to respond to this question or stated that they did not know.

5.40 Some respondents raised points which have been addressed under question 2 above.

Our response

5.41 The responses were broadly supportive and we propose to go ahead with the amendments.

Annotations made to an entry in the register

What we proposed

5.42 We proposed amending 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.

5.43 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.

What we heard

Question 5 - Do you agree with the proposed changes on applications for an annotation to an entry in the register?		
Yes	30	41.1%
No	11	15.1%
Don't know	7	9.6%

Skipped question	25	34.2%
Total	73	100%

5.44 41.1% of respondents agreed with this proposal and 15.1% disagreed. 43.6% of respondents chose not to respond to this question or stated that they did not know.

5.45 An organisation commented that, while they agreed that a person who had been removed from the register previously for failing to comply with the indemnity requirements should be obliged to provide a copy of their insurance policy or other indemnity arrangement, they should also be subject to a 'review period', during which they would need to provide evidence of continued indemnity cover, until the registrar was satisfied that this additional monitoring was no longer necessary.

Our response

5.46 We propose to go ahead with the amendments, subject to the same minor amendment referred to at paragraph 5.32 above, made upon advice from Privy Council advisers. The amendment removes the express provision requiring an applicant who has been removed from the register previously for failing to comply with the indemnity requirements 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. Instead of an express provision, we will simply request that additional evidence from all such applicants under the Registrar's power to do so. This avoids unnecessary duplication of information-gathering powers.

5.47 As set out above, the rules would allow us to request evidence of indemnity arrangements from a registrant by issuing a notice. We might want to do this if, for example, concerns were raised that a person who had provided evidence of indemnity cover in order to be restored to the register had cancelled that cover shortly afterwards. It would seem preferable not to state a defined period of continued monitoring in such circumstances but to allow for a risk-based proportionate approach.

Renewal of an annotation made to an entry in the register

What we proposed

5.48 We proposed amending 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. The registrar would be able to require the applicant to provide further information about their indemnity arrangements.

What we heard

Question 6 - Do you agree with the proposed changes on applications for renewal of an annotation to an entry in the register?		
Yes	29	39.7%
No	10	13.7%
Don't know	8	11.0%
Skipped question	26	35.6%
Total	73	100%

- 5.49 39.7% of respondents agreed with this proposal and 13.7% disagreed. 46.6% of respondents chose not to respond to this question or stated that they did not know.
- 5.50 One respondent queried whether a registrant would be required to maintain an indemnity arrangement at a level which would cover practice relating to their annotation, such as independent prescribing, even if their current practice did not entail making use of that annotation.

Our response

- 5.51 We propose to go ahead with the amendments. An applicant for renewal of an annotation would have to specify whether, if the annotation were to be renewed, they would have an indemnity arrangement in force providing appropriate cover. Their indemnity cover would need to be appropriate for their practice: if they were not making use of their annotation for a period, they would need to ensure that their indemnity arrangements were appropriate for their current practice, and that they would have appropriate cover in place when they resumed making use of their annotation.

Restoration of an entry in the register

What we proposed

- 5.52 We proposed amending 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

- 5.53 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.
- 5.54 An applicant for restoration would have to specify whether they hold evidence demonstrating that they have the necessary knowledge of English.

What we heard

Question 7 - Do you agree with the proposed changes on applications for restoration of an entry in the register?		
Yes	33	45.2%
No	6	8.2%
Don't know	7	9.6%
Skipped question	27	37.0%
Total	73	100%

- 5.55 45.2% of respondents agreed with this proposal and 8.2% disagreed. 46.6% of respondents chose not to respond to this question or stated that they did not know.
- 5.56 Some respondents raised points which have been addressed under questions 2 and 5 above.

Our response

- 5.57 The responses were broadly supportive and we propose to go ahead with the amendments, subject to the same minor amendment referred to at paragraph 5.32 and 5.45 above, made upon advice from Privy Council advisers. The amendment removes the express provision requiring an applicant who has been removed from the register previously for failing to comply with the indemnity requirements 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. Instead of an express provision, we will simply request that additional evidence from all such applicants under the Registrar's power to do so. This avoids unnecessary duplication of information-gathering powers.

Restoration of an annotation to an entry in the register

What we proposed

- 5.58 We proposed amending 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.
- 5.59 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.

What we heard

Question 8 - Do you agree with the proposed changes on applications for restoration of an annotation to an entry in the register?		
Yes	31	42.5%
No	8	11.0%
Don't know	6	8.2%
Skipped question	28	38.4%
Total	73	100%

- 5.60 42.5% of respondents agreed with this proposal and 11% disagreed. 46.6% of respondents chose not to respond to this question or stated that they did not know.
- 5.61 One respondent raised points which have been addressed under question 5 above.

Our response

- 5.62 The responses were broadly supportive and we propose to go ahead with the amendments, subject to the same minor amendment referred to at paragraph 5.32, 5.45 and 5.55 above, made upon advice from Privy Council advisers. The amendment removes the express provision requiring an applicant who has been removed from the register previously for failing to comply with the indemnity requirements 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. Instead of an express provision, we will simply request that additional evidence from all such

applicants under the Registrar's power to do so. This avoids unnecessary duplication of information-gathering powers.

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

- 6.1 This section covers amendments to The General Pharmaceutical Council (Fitness to Practise and Disqualification etc) Rules 2010 (S.I. 2010/1615). We proposed changes 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.

What we proposed

Interpretation

- 6.2 We proposed amending 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).

Initial action in respect of allegations

- 6.3 We proposed amending rule 6 of the Fitness to 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. 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 the knowledge of English allegation, directly to the Fitness to Practise Committee. Alternatively, the registrar may refer the misconduct allegation directly to the Fitness to Practise Committee without the knowledge of English allegation.

Notices of referral and documents to be supplied to persons concerned

- 6.4 We proposed amending 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. 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.

Applications for restoration

- 6.5 We proposed amending 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 the evidence of their fitness to return to practice. This could include undertaking an examination or assessment of their knowledge of English and providing the result to the registrar.

Procedures of the Investigating Committee

- 6.6 We proposed amending 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 the knowledge of English allegation. Alternatively, the registrar may refer the misconduct allegation directly to the Fitness to Practise Committee without the knowledge of English allegation.

Action upon referral of an allegation

- 6.7 We proposed amending 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.

Evidence

- 6.8 We proposed amending 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.

What we heard

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?		
Yes	37	50.7%
No	3	4.1%
Don't know	4	5.5%
Skipped question	29	39.7%
Total	73	100%

6.9 50.7% of respondents agreed with this proposal and 4.1% disagreed. 45.2% of respondents chose not to respond to this question or stated that they did not know.

6.10 A pharmacy organisation commented that knowledge of English was a prerequisite for registration, and so a person must provide evidence of an examination or assessment. Another said that it was important that these changes were considered as necessary, as patient safety was paramount.

Our response

6.11 The responses were broadly supportive and we propose to go ahead with the amendments.

7. Equality, diversity and inclusion

7.1 We prepared an equality impact assessment (EIA) on the draft GPhC (Amendment of Miscellaneous Provisions) Rules and published this on our website, to assist those responding to the consultation which you can find at www.pharmacyregulation.org/sites/default/files/amendments_rules_2015_equality_analysis.pdf

No further issues relating to equality, diversity and inclusion were raised in consultation responses.

8. Other comments

What we asked

- 8.1 We asked for any further comments about the draft GPhC (Amendment of Miscellaneous Provisions) Rules.

What we heard

Question 10 - Do you have any other comments you want to make?

- 8.2 Some of the responses received to this question have been addressed elsewhere in this report.
- 8.3 One organisation drew our attention to comments it had made to the Department of Health in response to its consultation on the Health Care and Associated Professions (Indemnity Arrangements) Order. They supported the rationale for regulators to be able to remove registrants from the register, or take fitness to practise action against them, in the event of non-compliance with the indemnity requirements. They also said that it would be important to ensure that decisions about whether to remove someone from the register administratively or to use the fitness to practise route were made in the interests of public protection. They believed there was a potential for bias towards administrative removal, as the less onerous option, and pointed out that the Professional Standards Authority did not have power to review these decisions to ensure they were in the public interest. On the other hand, they noted that decisions must be fair and equitable to the registrant, given the potential impact of fitness to practise proceedings on them; and expressed a wish to see some consistency both within each regulator and across regulators about cases which result in fitness to practise proceedings. Other potential challenges noted were how to deal with non-compliance if a case was referred to a fitness to practise panel but no impairment was found, or how to avoid situations where fitness to practise action could not be taken because the person had been removed from the register administratively for non-compliance with the indemnity requirements.
- 8.4 One respondent thought that the proposals would help to provide a stronger workforce, embodying professionalism. An organisation commented that it supported the proposals as they would enhance patient care and safety.

Our response

- 8.5 If a registrant did not have appropriate indemnity cover or failed to comply with the rules, they could be removed from the register administratively. Alternatively, the failure could be treated as misconduct and considered for referral as a fitness to practise case.

- 8.6 Administrative removal would be a proportionate approach which avoids the lengthy, costly alternative of fitness to practise procedures, the costs of which are borne by registrants as a whole. The person concerned would also have a right of appeal to the Appeals Committee. That is not to say that fitness to practise action might not be appropriate in some circumstances, for example if a registrant had had a number of fitness to practise issues and then failed to comply with the indemnity requirements, it might be thought appropriate to refer the matter to the Fitness to Practise Committee so that they could consider whether the person concerned should be removed from the register and then be unable to apply for restoration within five years. The Fitness to Practise Committee could also exercise its power under article 56 of the Pharmacy Order to make an interim suspension order if necessary.
- 8.7 If a person was removed from the register administratively for failure to comply with the indemnity requirements and a fitness to practise concern was then raised, that would need to be recorded for consideration in the event that the person applied to return to the register.
- 8.8 The procedure for administrative removal from the register for non-compliance with the indemnity requirements does not appear in the rules themselves, as we do not have powers to make such rules. We nevertheless plan to use internal guidance and a standard procedure for any such removals, to help ensure a consistent approach.
- 8.9 We are grateful for the feedback we have received. We will continue to keep the content of our rules under review.

Appendix 1: Respondents to the consultation

We received 73 responses to the consultation, 33 from individuals and 9 from organisations. Below is a list of organisations that responded to the consultation (one organisation did not identify itself).

Responses from organisations

Aneurin Bevan Community Health Council

Association of Pharmacy Technicians UK

Community Pharmacy Wales

Guild of Healthcare Pharmacists

Pharmacists' Defence Association

PharmacyVoice

Professional Standards Authority

Rowlands Pharmacy

General Pharmaceutical Council
25 Canada Square
London
E14 5LQ

T: 020 3713 8000

W: pharmacyregulation.org

E: info@pharmacyregulation.org

Twitter: [@TheGPhC](https://twitter.com/TheGPhC)

Facebook: [Facebook.com/TheGPhC](https://www.facebook.com/TheGPhC)

LinkedIn: [LinkedIn.com/company/general-pharmaceutical-council](https://www.linkedin.com/company/general-pharmaceutical-council)