Meeting of the Council  
Thursday, 10 September 2015  
1:15pm to 4:00pm  
Council Room, 25 Canada Square, London E14 5LQ

Agenda

Public business

1. Attendance and introductory remarks
   Nigel Clarke

2. Declarations of interest
   All
   Public items

3. Minutes of last meeting
   Nigel Clarke
   Public session 11 June 2015

4. Actions and matters arising
   Nigel Clarke

5. Strategic plan 2016-19
   15.09.C.01
   For approval
   Hugh Simpson

6. Registration Assessment and Board of Assessors’
   Report - June 2015
   15.09.C.02
   For discussion
   Damian Day

7. Consultation: draft rules on indemnity and
   language competence
   15.09.C.03
   For approval
   Christine Gray

8. Consultation: draft guidance on evidence of
   English language skills
   15.09.C.04
   For approval
   Martha Pawluczyk

9. Next steps for CPD call and review
   15.09.C.05
   For approval
   Osama Ammar

10. Chief Executive and Registrar’s report
    15.09.C.06
    For noting
    Duncan Rudkin

11. Professional Standards Authority performance
    review report 2014-15
    15.09.C.07
    For noting
    Lyn Wibberley

12. Embedding learning from the Mid Staffordshire
    Public Inquiry
    15.09.C.08
    For noting
    Hugh Simpson

13. Performance monitoring
    For noting
    15.09.C.09
    Duncan Rudkin
14. **Unconfirmed minutes of the Audit and Risk Committee, 23 July 2015**
   For noting
   Duncan Rudkin

15. **Policy and procedure review**
   For approval
   Matthew Hayday

16. **Any other public business**
   Nigel Clarke

**Confidential business**

1. **Declarations of interest**
   Confidential items
   All

2. **Minutes of last meeting**
   Confidential session 10 June 2015
   Nigel Clarke

3. **Confidential actions and matters arising**
   Nigel Clarke

4. **Any other confidential business**
   Nigel Clarke

**Date of next meeting**
Thursday, 15 October 2015
Minutes of the Council meeting held on Thursday, 11 June 2015 at 25 Canada Square, London, at 10:25am

Minutes of the public session

Present

Nigel Clarke – Chair
Alan Kershaw (from 32.1)
Berwyn Owen
David Prince
Digby Emson (to 32.1)
Evelyn McPhail
Liz Kay
Mary Elford
Mohammed Hussain
Samantha Quaye
Sarah Brown
Soraya Dhillon
Judy Worthington

Apologies

Tina Funnell
Bernard Kelly, Director of Resources and Customer Services (non-member)

In attendance

Duncan Rudkin (Chief Executive and Registrar)
Claire Bryce Smith (Director of Inspection and Fitness to Practise)
Vivienne Murch (Head of Organisational Development & People Strategy)
Lyn Wibberley (Head of Executive Office)
Matthew Hayday (Head of Governance)
Paula Woodward (Council Secretary)
Damian Day (Head of Education)
Priya Warner (Head of Standards & Fitness to Practise)
Mark Voce (Head of Inspection Team)
Chris Alder (Head of Professionals Regulation)
Terry Orford (Head of Customer Services)
Rachael Oliver (Head of Communications)

23. Attendance and introductory remarks

23.1. The Chair welcomed members, staff and observers to the meeting.

23.2. Members congratulated Samantha Quaye on being shortlisted for a Future Leaders award from Women and the City, an organisation which aims to promote, recognise and reward female talent.

23.3. Apologies were received from Tina Funnell and Bernard Kelly (non-member).
24. **DECLARATIONS OF INTEREST**

24.1. The following declarations of interest were made.

- **Item 5: 2015 fees rules and consultation analysis**
  All registrant members: Samantha Quaye, Soraya Dhillon, Digby Emson, Liz Kay, Berwyn Owen, Mohammed Hussain, Berwyn Owen

- **Item 7: review of current CPD framework**
  All registrant members: Samantha Quaye, Soraya Dhillon, Digby Emson, Liz Kay, Berwyn Owen, Mohammed Hussain, Berwyn Owen

25. **MINUTES OF THE PUBLIC SESSION OF THE PREVIOUS MEETING**

25.1. The minutes of the public sessions of the meetings held on Thursday, 16 April 2015 and on Thursday, 7 May 2015 were agreed as a true record.

26. **ACTIONS AND MATTERS ARISING**

26.1. There were no further updates to the actions or matters arising.

27. **2015 FEES RULES AND CONSULTATION ANALYSIS**

27.1. Hugh Simpson (HS) summarised the main points in the paper including the basis for the proposals, and outlined the feedback that had been received during the consultation.

27.2. HS reminded members that a report on allocation of the costs of regulation had been prepared earlier in the year which set as robust a basis for the proposed fees as could be ascertained at the time. HS reported that further work was being carried out to ensure that more detail about the various areas of cost could be identified.

27.3. Members discussed the impact of the fee increases on registrants and noted that there was currently no provision for low income registrants.

27.4. The Council noted that the organisation needed to be very clear about the core purpose of regulation and its costs. It should also clearly demonstrate the impact of efficiency savings that had already taken place, as well as the expected impact of the efficiency and effectiveness programme which formed a key part of the organisation’s corporate plan.

27.5. The Council also noted that having a more detailed picture of the costs would help the organisation accurately reflect the costs through the various fees, and would help to reduce any unnecessary fluctuations in fees. However, the Council also noted that the costs forecast would be affected by other factors, such as changes to the way inspections are planned and carried out, and any further rise in the number of concerns about registrants.

27.6. The Council:

   i. noted the analysis of the fees rules consultation;
ii. approved the changes to fees summarised at section 5 of the paper; and

iii. made The General Pharmaceutical Council (Registration and Renewal Fees) Rules 2015 (appendix 2) and agreed that the GPhC’s corporate seal be affixed to these rules.

28. **Health and Social Care (Safety and Quality) Act 2015**

28.1. HS outlined the provisions of the Act and drew members’ attention to the key areas that would affect the work of pharmacy professionals and the GPhC.

28.2. The Council noted the paper.

29. **Review of Current CPD Framework**

29.1. Osama Ammar (OA) introduced the paper to members, drawing their attention to the main points.

29.2. During the discussion, members noted that the review would take into account data from fitness to practise and the approach being taken by other regulators, with a particular focus on the balance of burden versus benefits for individual registrants. Members also noted that the review aimed to develop a framework that focussed on outcomes rather than outputs.

29.3. The Council noted that a further paper would be presented in September 2015 outlining recommendations and timings for changes to the current CPD requirements and systems.

29.4. The Council is asked noted the report.

30. **Corporate Plan Update and Performance Monitoring Report**

30.1. Claire Bryce Smith (CBS) outlined the key points of the inspections and fitness to practise (FtP) performance figures.

30.2. CBS and Mark Voce (MV) responded to some detailed questions about the way inspections were planned and carried out, particularly the way that various information sources, both internal and external, could be used to inform that planning.

30.3. CBS and Chris Alder (CA) responded to some detailed questions about the various strands of work being carried out by the fitness to practise teams and the management of the increased workload.

30.4. The Council noted that the FtP capacity model was being regularly reviewed and revised to optimise the throughput of cases. The Council also noted that the development of a number of memoranda of understanding (MoUs) with other organisations were beginning to show benefits, particularly by helping staff contact the right people and streamlining the process of allowing information to be provided.
30.5. Members suggested that, when the format of the report was next reviewed, the number of inspections carried out should be separated into those that were planned and those that resulted from a concern.

30.6. ACTION: An outdated version of the corporate plan update had been circulated in the papers. The correct version of the report to be circulated to members and the item deferred to the next Council meeting in July.

30.7. The Council noted the performance monitoring report.

31. CHIEF EXECUTIVE AND REGISTRAR’S REPORT

31.1. DR outlined the main points in the report.

31.2. The Council noted the report.

32. REMUNERATION COMMITTEE UNCONFIRMED MINUTES AND ANNUAL REPORT

32.1. Alan Kershaw was present from this point. Digby Emson left the meeting.

32.2. Liz Kay (LK) drew members’ attention to the key points of the committee’s last meeting, particularly the results of the staff survey and the annual salary changes.

32.3. LK also outlined the main points in the committee’s annual report to Council, particularly those areas which demonstrated how the committee had carried out the duties set out in its terms of reference.

32.4. The Council noted the unconfirmed minutes of the Remuneration Committee held on 23 April 2015.

32.5. The Council noted the Remuneration Committee’s annual report.

33. AUDIT AND RISK COMMITTEE UNCONFIRMED MINUTES AND ANNUAL REPORT

33.1. David Prince (DP) drew members’ attention to the key points of the committee’s last meeting, particularly the scrutiny of the annual report and accounts, and its discussions around the reappointment of the external auditors.

33.2. DP also outlined the main points in the committee’s annual report to Council, particularly those areas which demonstrated how the committee had carried out the duties set out in its terms of reference.

33.3. The Council noted the unconfirmed minutes of the Audit and Risk Committee held on 23 April 2015.

33.4. The Council noted the Audit and Risk Committee’s annual report.

34. ANNUAL REPORT AND ACCOUNTS 2014-15

34.1. DR drew members’ attention to the key points in the annual report, including the statement of internal control, and the letter of representation. He informed the Council that the report had been reviewed by the Audit and Risk Committee at its meeting in May.
34.2. Rachael Oliver (RO) outlined the process for laying the report in parliament and its subsequent publication online.

34.3. The Council:
   i. approved the combined annual report; annual accounts and fitness to practise report for 2014-15, subject to the correction of typographical errors;
   ii. authorised the Chair to sign the letter of representation as required by the auditors.

35. APPOINTMENT OF EXTERNAL AUDITORS
35.1. The Council appointed Grant Thornton as the GPhC’s external auditors for the year 2015-16.

36. ANY OTHER PUBLIC BUSINESS
36.1. Members noted the dates of Council meetings and workshops for 2016.
36.2. There being no further public business, the meeting closed at 1:45pm.

DATE OF NEXT MEETING
Thursday 10 September 2015
Public business

Strategic Plan 2016-19

Purpose
To agree the GPhC Strategic Plan for 2016-2019.

Recommendations
The Council is asked to agree the Strategic Plan 2016-19 which appears in draft at Appendix 1.

1. Introduction
1.1 We have a statutory obligation to submit a strategic plan annually to the Privy Council Office, to be laid before the UK Parliament and the Scottish Parliament.
1.2 Attached in appendix 1 is the proposed draft Strategic Plan 2016-19.
1.3 As in previous years, the new strategic plan will be complemented by a more detailed corporate plan (due to be considered by Council at its meeting in February 2016).
1.4 The strategic plan summarises what the organisation will be aiming to achieve. The corporate plan will set out how we plan to do that, and how we will report on progress.

2. Overview
2.1 The proposed plan reflects Council’s vision for regulation to play its part in improving quality, of which safety is a critical element. It builds on the themes presented in our previous Strategic Plan 2015-18 and proposes four key aims.
2.2 Without any major divergence from Council’s strategic direction, the proposed strategic plan has been updated to:
   • Reinforce Council’s view that for regulation to be effective, we must consider the impact of our policies and reforms, particularly in
relation to education and training, upon the pharmacy team as a whole.

- Address our commitment to efficiency and effectiveness as a longer term cultural and strategic goal, not as a short term budgeting or cost cutting exercise.
- Build in the importance of considering longer term changes in pharmacy practice and models of healthcare delivery into our work.

3. **Key considerations**

3.1 The draft Strategic Plan (2016-19) has been designed to provide greater information about our strategic approach and the context in which we operate than previous plans. These explicitly build on the ‘themes’ set out in previous strategic plans and are set out in the new section ‘Our strategic approach’. The four thematic areas covered are:

i. Promoting a culture of patient-centred professionalism;

ii. Putting patients and the public at the heart of what we do;

iii. Effective and efficient regulation; and,

iv. Keeping pace with changes in pharmacy.

3.2 We are proposing four strategic ‘aims’ which are designed to provide improved clarity on those parts of the strategic plan which will need clear work programmes within the corporate plan. The proposed strategic aims are:

i. Delivering efficient and effective regulatory services

ii. Ensuring the pharmacy team is able to meet the needs of patients now and in the future

iii. Using the knowledge gained from our regulatory services and from our work with others in order to promote improvement in the quality of pharmacy care and services

iv. Enhancing our understanding of issues, risks and opportunities in pharmacy so that pharmacy regulation is flexible and adapts quickly to the needs of patients and risks within the sector

4. **Equality and diversity implications**

4.1 Equality, diversity and inclusion issues will be considered in all workstreams which follow as part of our corporate planning.

4.2 The draft strategic plan specifically highlights the diversity in healthcare and pharmacy within and between the home countries of Great Britain and gives priority to our understanding and engaging effectively with different contexts in England, Scotland and Wales.
5. Communications
5.1 The strategic plan itself, once laid before the UK Parliament and the Scottish Parliament, serves a formal communication purpose as one of the core documents, alongside our Annual Report, to which the Council will be held accountable.
5.2 The strategic plan will also inform day to day operational and corporate communications, as an important source document, to be drawn on for authoritative information about the Council’s aims and priorities.

6. Resource implications
6.1 This strategic plan reflects a continuity of approach and as such does not include any new specific initiatives. However, as is usual, the detailed evaluation of any resource implications is taking place as part of our annual corporate and budget planning process.
6.2 As set out in this cover paper and the strategic plan (2016-19) we have put additional emphasis on the need for efficiency and effectiveness both as part of long term cultural and strategic focus, as well as the need for us to continue to demonstrate our commitment to managing costs and identifying savings.

7. Risk implications
7.1 A key priority will be for us to communicate effectively with our stakeholders the key points set out within the strategic plan including our regulatory approach and how we engage with and work with others.

8. Monitoring and review
8.1 The strategic plan is reviewed by the Council annually with updates on progress reported to Council through the corporate plan progress reports.

Recommendations
The Council is asked to agree the Strategic Plan 2016-19 which appears in draft at Appendix 1.

Hugh Simpson, Director of Strategy
General Pharmaceutical Council
hugh.simpson@pharmacyregulation.org
Tel 020 3713 7803
26 August 2015
2016-19 strategic plan

To be published after it has been laid in the UK and Scottish Parliaments
Council meeting 10 September 2015

Public business

The June 2015 Registration Assessment

Purpose
To update Council on the June 2015 Registration Assessment including the Board of Assessors’ report.

Recommendations
The Council is asked to note the report from the Board of Assessors.

1. Introduction

1.1 Passing the GPhC’s registration assessment is a pre-requisite for applying to register as a pharmacist\(^1\). There are two sittings every year, in June and September. This paper discusses the June 2015 sitting.

1.2 The Registration Assessment is set and moderated by the Board of Assessors which operates independently from the GPhC. The Board presents a paper to the GPhC’s Council after each sitting and Board’s report on the June sitting is appendix 1.

2. The Board’s report

2.1 The Board’s report is a comprehensive overview of the June sitting. It provides a range of statistical data about the June 2015 registration assessment. The data includes pass and fail rates by sector, gender, ethnicity and previous sittings.

2.2 In addition, for the first time the report includes information on pass rates, by pharmacy school.

\(^1\) Except for EEA pharmacists.
3. **Issues for consideration**

3.1 Council has raised, through its strategic plan (2015-18), the importance of using information and knowledge gained from our work to both inform our regulatory work and to inform wider debates within the healthcare sector in general and pharmacy as a whole.

3.2 Consistent with this strategy we are able to access increasing amounts of data and analyse a range of potential issues highlighted by the registration assessment. In May we published data covering pass rates for the registration assessment (2011-14).

3.3 Data within Board reports have increased year on year, which has in turn given us an increased understanding of cohorts and has allowed us to begin to identify trends and reach some preliminary views about issues.

3.4 In relation to the June report, we think three trends in particular should be drawn to Council’s attention, although others may emerge after further work has been undertaken.

3.5 *Performance by sector:* the data from the last few years shows that, as cohorts, hospital candidates always perform better than community candidates and for this sitting the difference is particularly pronounced - the pass rate for hospital-based candidates being 20% higher than for community-based candidates.

3.6 This persistent disparity is a cause for concern but further work needs to be undertaken before drawing more definitive conclusions about causation, given the size of and variety in the community pharmacy training sector.

3.7 *Performance by cohorts:* In the last few years pass rates have been more volatile and also lower than in the past. We recognise that the reasons for candidate performance and pass rates are the subject of much speculation and assertion. It is our intention to continue to study the data in detail and where correlations or specific issues of concern are highlighted, identify the most appropriate mechanisms to correctly attribute causation factors and consider what actions for the GPhC, or others, may be appropriate.

3.8 *Performance by ethnicity:* Candidate performance by ethnicity continues to vary significantly. We are in the final stages of commissioning qualitative research into the experiences of Black-African candidates in pre-registration training because this group tends to perform particularly poorly in comparison to others. Depending on the outcome of this work we may need to broaden its scope.
4. **Next steps**

4.1 Our understanding of performance in the Registration Assessment and pre-registration training has improved significantly in the last few years but there is further work to be done to consider issues and trends in more detail.

4.2 It is inevitable that as we publish increasing amounts of data and information, there will be increased scrutiny on both our work and those we regulate. This is consistent with wider principles of good regulation, not least our commitment to transparency, as well as commitments in our current strategic plan\(^2\) summarised below:

   i. *We will be analysing data from our regulatory functions and critically scrutinising intelligence about pharmacy issues and risks, in order to keep our standards up to date, and to inform targeted regulatory interventions across all our areas of responsibility and then to evaluate their impact.*

   ii. *We will be playing back to the profession and to pharmacy stakeholders the feedback we gather from people using pharmacy services, and from our assurance activities, to inform their work to improve quality in pharmacy.*

   iii. *We will be publishing regular reports, based on our learning from data, information and intelligence gathered, to highlight issues and opportunities for improvement within pharmacy.*

4.3 As part of our own corporate planning we will assess what further analysis or research the GPhC should carry out to understand better the implications for our work. In addition, we will work with others with an interest in this area who may be better placed or may wish to use the information provided to contribute further to debates about pharmacy education and training.

5. **Equality and diversity implications**

5.1 Equality and diversity issues have been discussed above in 2.2.

6. **Communications**

6.1 The data published by the GPhC will be of interest to a wide range of stakeholders. The Board’s report will be shared directly with schools of pharmacy, the BPSA, pre-registration training providers and pre-registration funders.

7. **Resource implications**

7.1 There are no resource implications for the GPhC emerging directly from the Board’s report or this cover paper. However, as referenced earlier, we will

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need to consider as part of our corporate planning process what, if any, further research and analysis is required.

8. Risk implications

8.1 It is critical that we continue to review the operation of our registration assessment to ensure it continues to provide assurance to the public about the fitness to practise of those who join our register. The work of the Board of Assessors, operating independently to the GPhC is a critical part of this. The Board will continue to analyse robustly the performance of the registration assessment and report publicly to Council.

Recommendations

The Council is asked to note the report from the Board of Assessors.

Damian Day, Head of Education
General Pharmaceutical Council
damian.day@pharmacyregulation.org
26 August 2015
Board of Assessors’ report to the General Pharmaceutical Council
June 2015 Registration Assessment

1. Introduction

1.1 The initial education and training of pharmacists in Great Britain is:

- an accredited four-year MPharm degree\(^1\); then
- 52 weeks of pre-registration training; and
- the GPhC’s Registration Assessment.

1.2 During pre-registration training, trainees are signed-off on four occasions by their tutor – at 13, 26, 39 and 52 weeks. Trainees must have been signed off as ‘satisfactory’ or better at 39 weeks to be eligible to enter for a sitting of the Registration Assessment.

1.3 Candidates with a specific need may ask for an adjustment to be made in the conduct of the assessment. Candidates with specific needs may sit the assessment in a separate adjustments room.

1.4 The Registration Assessment is a multiple choice question examination with two papers: a morning closed book paper and an afternoon open book paper. In the closed book paper, no reference sources can be used; in the open book paper, specified reference sources can be used. Calculators are not permitted.

1.5 There are 90 questions in the closed book paper, to be answered in 1 hour 30 minutes, and 80 questions in the open book paper, to be answered in 2 hours 30 minutes. The open book paper includes 20 dedicated calculations questions which must be passed separately and in addition to the Assessment being passed overall.

2. Role of the Board of Assessors

2.1 The GPhC is responsible for running its national Registration Assessment. Operational matters are dealt with internally but papers are set by an independent, appointed body, the Board of Assessors.

2.2 The Board comprises a chair\(^2\) and deputy chair, both pharmacists, and nine other pharmacist members (a mixture of pharmacists working in schools of pharmacy and pharmacists in practice). Two other members of the Board are non pharmacists but both are assessment experts: one is a doctor with expertise in education and

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\(^1\) Non-EEA pharmacists study on a 1-year Overseas Pharmacists’ Assessment Programme (OSPAP), not an MPharm degree

\(^2\) Currently vacant.
assessment and the other is a consultant in healthcare assessment. Within the Board there is also pharmacist representation from England, Scotland and Wales.

2.3 All decisions about questions, papers, candidates and pass marks are made by the Board.

2.4 The Board is supported by the GPhC’s Education team.

3. Reporting to the GPhC

3.1 The Board of Assessors produces two reports for the GPhC annually, one after each of the sittings in June and September.

3.2 This report relates to the June 2015 sitting.

4. June 2015 statistics

4.1 All candidate numbers

<table>
<thead>
<tr>
<th>No. of candidates sitting</th>
<th>2811</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of first sitting candidates</td>
<td>2621</td>
</tr>
<tr>
<td>Number of second sitting candidates</td>
<td>116</td>
</tr>
<tr>
<td>Number of third sitting candidates</td>
<td>74</td>
</tr>
</tbody>
</table>

4.2 All candidate performance - % pass/fail

– 2077 candidates passed and 734 candidates failed.
– This year’s pass rate of 74% is lower than in previous years. The next lowest pass rate was 78% in June 2013.
4.3 All candidate performance – pass rate by attempt

- A finding consistent with previous sittings is that resit candidates performed less well than first attempt candidates.

4.4 First attempt candidate performance – home students vs OSPAP\(^3\) students

- There is a 3% difference in pass rates between candidates who studied wholly in GB (‘Home’ candidates) and candidates whose primary pharmacy qualification was gained outside the EEA (‘OSPAP’ candidates). There were 2549 MPharm candidates and 72 OSPAP candidates. Given the small number of OSPAP candidates, nothing can be inferred reliably from the difference in pass rates.

\(^3\) Overseas pharmacists' assessment programme
4.5 First attempt candidate performance – performance by gender

- Female candidates performed better than male candidates by 4%.
- 1658 candidates were female and 963 were male.

4.6 First attempt candidate performance – performance by training sector

- There were 675 hospital-based candidates (26% of the total number of candidates) and 1944 community-based candidates (74%). A finding consistent with previous sittings is that hospital-based candidates performed better than community-based candidates.
- There were two candidates who spent six months training in academia and there were no industry-based candidates.
4.7 First attempt candidate performance – performance by ethnicity (categories with >100 candidates)

- This figure presents data on the performance of the main self-designated ethnic categories. Other categories, with <100 members, have been excluded on the basis that the data are less reliable for less populous categories.
- The national pass rate is lower this year than last year but the rank ordering of pass rates by ethnicity has changed very little.

4.8 Candidate performance by school of pharmacy

<table>
<thead>
<tr>
<th>School of pharmacy (MPharm)</th>
<th>Pass rate (%)</th>
<th>Number of candidates</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aston University</td>
<td>84</td>
<td>117</td>
</tr>
<tr>
<td>University of Bath</td>
<td>90</td>
<td>103</td>
</tr>
<tr>
<td>University of Bradford (4-year and 5-year combined)</td>
<td>63</td>
<td>159</td>
</tr>
<tr>
<td>University of Brighton</td>
<td>63</td>
<td>86</td>
</tr>
<tr>
<td>Cardiff University</td>
<td>86</td>
<td>110</td>
</tr>
<tr>
<td>University of Central Lancashire</td>
<td>68</td>
<td>72</td>
</tr>
<tr>
<td>De Montfort University</td>
<td>73</td>
<td>111</td>
</tr>
<tr>
<td>University of East Anglia</td>
<td>84</td>
<td>98</td>
</tr>
<tr>
<td>University of Hertfordshire</td>
<td>48</td>
<td>110</td>
</tr>
<tr>
<td>University of Huddersfield</td>
<td>78</td>
<td>54</td>
</tr>
<tr>
<td>Keele University</td>
<td>75</td>
<td>69</td>
</tr>
<tr>
<td>King’s College London</td>
<td>86</td>
<td>103</td>
</tr>
<tr>
<td>Kingston University London</td>
<td>67</td>
<td>83</td>
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<tr>
<td>Liverpool John Moores University</td>
<td>74</td>
<td>104</td>
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<tr>
<td>University College London</td>
<td>73</td>
<td>147</td>
</tr>
<tr>
<td>School of pharmacy (MPharm)</td>
<td>Pass rate (%)</td>
<td>Number of candidates</td>
</tr>
<tr>
<td>-----------------------------</td>
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</tr>
<tr>
<td>University of Manchester</td>
<td>86</td>
<td>127</td>
</tr>
<tr>
<td>Medway School of Pharmacy</td>
<td>75</td>
<td>123</td>
</tr>
<tr>
<td>University of Nottingham</td>
<td>88</td>
<td>165</td>
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<tr>
<td>University of Portsmouth</td>
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<td>108</td>
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<tr>
<td>University of Reading</td>
<td>82</td>
<td>66</td>
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<tr>
<td>Robert Gordon University</td>
<td>86</td>
<td>111</td>
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<tr>
<td>University of Sunderland</td>
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<tr>
<td>University of Strathclyde</td>
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<td>119</td>
</tr>
<tr>
<td>University of Wolverhampton</td>
<td>54</td>
<td>63</td>
</tr>
</tbody>
</table>

- The range of percentage pass rates for MPharm degree candidates by school of pharmacy is 42% (90%-48%).
- OSPAP candidates: OSPAP data have not been presented because candidate numbers are so low for some providers that it might be possible to identify individuals.
- Northern Irish candidates: Most graduates from the two accredited Northern Irish schools of pharmacy enter pre-registration training in Northern Ireland and sit the PSNI’s Registration Examination. A very small number undertake pre-registration training in GB and sit the Registration Assessment. The data has not been presented because candidate numbers are so low that it might be possible to identify individuals.

4.9 Reasonable adjustments requests for specific needs
- Through its Adjustments Panel, the Board granted reasonable adjustments as follows:

<table>
<thead>
<tr>
<th>Status</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fully granted</td>
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<tr>
<td>Partially granted</td>
<td>6</td>
</tr>
<tr>
<td>Not granted</td>
<td>7</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Reason for request (significant categories)</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dyslexia</td>
<td>78</td>
</tr>
<tr>
<td>Anxiety/stress/panic attack</td>
<td>15</td>
</tr>
<tr>
<td>Muscular/joint ache/pain</td>
<td>14</td>
</tr>
<tr>
<td>Pregnancy-related symptoms</td>
<td>11</td>
</tr>
</tbody>
</table>

- All but two requests were for 25% additional time (some accompanied by other adjustments).
- Granting 148 adjustments represents an adjustment for 5.2% of candidates.
4.10 **Word count**

The word count for the paper in comparison to 2013 and 2014 papers is as follows:

<table>
<thead>
<tr>
<th>Paper</th>
<th>Closed book word count</th>
<th>Open book word count</th>
</tr>
</thead>
<tbody>
<tr>
<td>June 2013</td>
<td>5,968</td>
<td>5,433</td>
</tr>
<tr>
<td>June 2014</td>
<td>5,388</td>
<td>5,438</td>
</tr>
<tr>
<td>June 2015</td>
<td>5,805</td>
<td>4,930</td>
</tr>
</tbody>
</table>

5. **Discussion of the papers by the Board**

5.1 *Purpose and content of the Registration Assessment:*

The Board is clear that it must set papers which reflect day 1 practice, and that is the test applied to all questions. The papers are deliberately designed to contain a mix of easy, moderately difficult and difficult questions, in order to ensure that the papers discriminate effectively between candidates who meet the required standard and those who do not. Candidates should not assume that because they found some questions difficult, the overall standard is too high.

5.2 *Routine quality assurance of the paper:*

After a sitting, the performance of questions and the papers as a whole are analysed by the Board. As a result of the post-sitting analysis for June 2015, two questions were removed and, in the case of four questions, two answers were accepted. For these questions, there was one best answer (which candidates should have identified) but there was another which, while not the best answer, was plausible and clinically safe and therefore was accepted. The removal of two questions meant that the total number of questions in the paper was reduced from 170 to 168. When questions are removed, the Board always checks that individual candidates are not disadvantaged by the questions having been removed.

5.3 **Pass mark:**

The Board considered (1) the pass mark for the Assessment as a whole and (2) the calculations pass mark. It was agreed that the pass mark for the Assessment as a whole should be lowered from 117/168 to 114/168 but that there was no justification for adjusting the calculations pass mark, which was left at 14/20. This was based on statistical data evidencing the relative difficulty of the paper.

5.4 **Feedback:**

The BPSA presented a report to the GPhC about the June 2015 sitting. It was passed on to the Board and discussed at its full meeting in July. The Board notes that the GPhC would be responding to the BPSA report. The Board also noted a survey undertaken by a pre-registration tutor/training provider and other feedback from trainees.

5.5 **Learning points:**

As it has done in previous years, the Board issued learning points for candidates and
pre-registration tutors. On this occasion the learning points included questions used in the paper. The Board hopes that using actual questions will aid understanding of the learning points.

5.6 **Paper creation and analysis:**
In the interests of transparency, the GPhC has created flowcharts showing the stages in the design of a paper and the analysis of paper performance. The Board hopes this will show that all relevant factors are taken into account before a final pass mark is agreed.

5.7 **Syllabus mapping:**
Part of the methodology for creating a paper requires every question to be mapped to a syllabus area. The number of questions from each syllabus area is pre-determined using rules that are applied consistently across all papers. The syllabus is broad because pharmacy is a broad discipline and if candidates encounter questions on topics that have not been tested in recent past papers, this does not mean that the questions are inappropriate.

5.8 **Sectoral relevance of questions:**
The majority of questions are relevant to all sectors of practice. A small number of questions are more relevant to one sector than another but these questions are balanced across sectors in each paper.

5.9 **Sectoral pass rates:**
The Board is concerned that the pass rate for community trainees is 20% lower than the pass rate for hospital trainees. There is always a difference in the pass rate in favour of the hospital sector, but it is particularly pronounced in this sitting.

5.10 **Controlling entry to the register:**
It remains the case that the Registration Assessment is never used to control numbers of trainees registering as pharmacists.

5.11 **Ramadan:**
In 2015 the June sitting was in the middle of Ramadan. On the basis of an equality impact assessment conducted by the GPhC’s Equality, Diversity and Inclusion Manager, the sitting was moved from a Friday to a Thursday, making it easier for Muslim students to attend Friday prayers. This was not an adjustment for a small minority of candidates as 833 candidates sitting in June identified themselves as Muslim.
The June 2016 sitting is also in Ramadan so it will be scheduled on a Thursday as well, for the same reason.

5.12 **Colour of the summary of product characteristics (SPC) reference document:**
The BPSA fed back that the colour of the SPC used was difficult for some candidates to read. The colour, Icy Blue, was chosen on the basis that it was a pastel shade sympathetic to dyslexic readers. The Board decided that in future, SPCs will be black text on white paper and candidates can request an alternative as part of a
reasonable adjustment request should this be necessary. Black on white is the colour of standard SPCs.

Board of Assessors
10th August 2015
Public business

Consultation: draft rules on indemnity and language competence

Purpose
To provide the Council with the proposed consultation on draft amendments to the GPhC’s Registration Rules, Fitness to Practise and Disqualification Rules, and Statutory Committees and their Advisers Rules.

Recommendations
The Council is asked to agree the content of the consultation on draft amendments to rules.

1. Introduction
1.1 The Council has the responsibility, under the Pharmacy Order 2010, to make rules in a number of areas. The changes proposed here would amend the GPhC’s Registration Rules, Fitness to Practise and Disqualification Rules, and Statutory Committees and their Advisers Rules.

1.2 The main purpose of these draft rules is to amend the Registration Rules and Fitness to Practise and Disqualification Rules to take account of changes to the Pharmacy Order concerning requirements for indemnity arrangements and for knowledge of the English language.

1.3 It is also proposed to take this opportunity to make some changes to the GPhC’s rules which were requested previously by parliamentary subordinate legislation committees. These relate to:

   - avoiding conflicts of interest arising from common membership of Fitness to Practise Committee panels and Appeals Committee panels; and
   - avoiding breach of Crown copyright relating to the front cover of a UK passport.

1.4 These proposals have been developed with input from Council members and statutory committee members. The Council is now asked to approve the consultation document on draft amendments to the rules covering: statutory committees; registration processes, and fitness to practise processes. It is
proposed that the Council will consider the draft consultation report and the final draft amendments rules in April 2016.

1.5 The detail of the proposed changes, together with the draft amendments rules, is set out in the draft consultation document at appendix 1. The Privy Council’s advisers (departments of health policy officials and solicitors) have provided informal clearance to the draft rules for the purpose of consultation.

2. **Equality and diversity implications**

2.1 An equality assessment of the draft rules will be published on the GPhC website during the consultation. Any further equality and diversity implications raised in responses will be covered in the consultation report.

3. **Communications**

3.1 The consultation will be published on the GPhC’s website. It will also be sent to a wide range of stakeholders and communicated to the pharmacy media. The consultation will run for 12 weeks and respondents will be able to respond online, by email or by post.

4. **Resource implications**

4.1 The launch and conduct of the consultation can be covered within existing resources.

5. **Risk implications**

5.1 Failure to consult appropriately on the proposed amendments to rules would mean that the GPhC would not be complying with its statutory duties.

6. **Monitoring and review**

6.1 The impact of the rules will initially be monitored through the consultation process and subsequently through performance monitoring reports submitted to the GPhC’s Council and published on our website www.pharmacyregulation.org

6.2 The outcome of the consultation process is scheduled to be reported to the Council in April 2016, when it is anticipated that the Council will make the rules.

6.3 The rules would be reviewed in the event of any relevant amendments to the Pharmacy Order or other need for legislative change.

**Recommendations**

The Council is asked to agree the content of the consultation on draft amendments to rules.

*Christine Gray, Rules Lead, General Pharmaceutical Council*
*christine.gray@pharmacyregulation.org,*
*tel 020 3713 7816 *
*20 August 2015*
DRAFT

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
The deadline for responding to this consultation is **XXday XX December 2015**.
Consultation on draft amendments to rules

1. Overview

The GPhC is consulting until **xxday xx 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 [www.pharmacyregulation.org/about-us/what-we-do/legislation/pharmacy-order-2010-and-rules](http://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 here [link](http://www.pharmacyregulation.org/about-us/what-we-do/legislation/pharmacy-order-2010-and-rules).
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 xxday xx 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 go to our website and fill in an online version there.

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

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 members of the public and, in particular, those members of the public who use or need the services of pharmacy professionals or services provided by a registered pharmacy.

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 principal functions include:

- maintaining a register of pharmacists, pharmacy technicians and pharmacy premises
- setting standards for conduct, ethics, proficiency, education and training, and continuing professional development
- setting and promoting standards for the safe and effective practice of pharmacy at registered pharmacies
- establishing fitness to practise requirements and monitoring pharmacy professionals’ fitness to practise, and
- dealing fairly and proportionately with complaints and concerns.

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 to 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’. 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 (S.I. 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 [link].

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 (S.I. 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 (S.I.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 (S.I. 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 [link].

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 Rules**

8.1 The amendments proposed in this section would affect the General Pharmaceutical Council (Fitness to Practise and Disqualification) Rules 2010 (S.I. 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**

8.3 This would amend 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 (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 link 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 xxday xx 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.

☐ 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
Section A - Responding as an individual

Please tell us your:
name:------------------------------------------------------------------------------------------------------------------
address:------------------------------------------------------------------------------------------------------------------
------------------------------------------------------------------------------------------------------------------
email:------------------------------------------------------------------------------------------------------------------

Where do you live?
☐ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ other (please give details)

Are you responding as:
☐ a pharmacy professional – please go to section A1
☐ a member of the public
☐ other (please give details)

Section A1 - Pharmacy professionals

Are you:
☐ a pharmacist
☐ a pharmacy technician

Please choose the option below which best describes the area you mainly work in:
☐ community pharmacy
☐ hospital pharmacy
☐ primary care organisation
☐ pharmacy education and training
☐ pharmaceutical industry
☐ other (please give details)
Section B: Responding on behalf of an organisation

Please tell us your:

name:---------------------------------------------------------------

job title:---------------------------------------------------------------

organisation:---------------------------------------------------------------

address:---------------------------------------------------------------

email:---------------------------------------------------------------
a contact name for enquiries:---------------------------------------------------------------

contact phone number:---------------------------------------------------------------

Is your organisation a:

☐ pharmacy organisation

☐ non-pharmacy organisation

Please choose the option below which best describes your organisation:

☐ body or organisation representing professionals

☐ body or organisation representing patients or the public

☐ body or organisation representing a trade or industry

☐ community pharmacy

☐ corporate multiple pharmacy

☐ independent pharmacy

☐ NHS organisation or group

☐ research, education or training organisation

☐ government department or organisation

☐ regulatory body

☐ other (please give details)
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.

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 1?

2. Do you agree with the proposed duty for registrants to provide information about their indemnity arrangements? (see sections 7.2-7.4 of the consultation document)
   - [ ] Yes
   - [ ] No
   - [ ] Don’t know

Do you have any further comments in response to question 2?
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?

☐ Yes  
☐ No  
☐ Don’t know

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?

☐ Yes  
☐ No  
☐ Don’t know

5. Do you agree that the proposed changes on applications for an annotation to an entry in the register?  
(see sections 7.13-7.14 of the consultation document)

☐ Yes  
☐ No  
☐ Don’t know
Do you have any further comments in response to question 5?

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

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)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 7?
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
☐ No
☐ Don’t know

Do you have any further comments in 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)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 9?
10. Do you have any other comments you want to make?
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
☐ British
☐ Irish
☐ Other

Black or Black British
☐ Caribbean
☐ African
☐ Other

Mixed
☐ White and black Caribbean
☐ White and black African
☐ other mixed (please give more information in the box below)

☐ White and Asian
☐ other Asian (please give more information in the box below)

Asian or Asian British
☐ Indian
☐ Pakistani
☐ other Asian (please give more information in the box below)

☐ Bangladeshi

☐ Chinese or Chinese British

☐ Other ethnic group
(please give more information in the box below)

What is your age?
Please tick one box

☐ 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 orientation?
Please tick one box
☐ heterosexual ☐ lesbian or gay ☐ bisexual ☐ other

What is your religion?
Please tick one box
☐ None ☐ Christian ☐ Buddhist ☐ Hindu
☐ Jewish ☐ Muslim ☐ Sikh
☐ Other (please give more information in the box below)

Do you consider that you have a disability?
Please tick one box
☐ Yes ☐ No
0 STATUTORY INSTRUMENTS

2015 No.

HEALTH CARE AND ASSOCIATED PROFESSIONS

PHARMACY


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

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)(iiia) 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 arrangement which provides appropriate cover in relation to the applicant, and”; and

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

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(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).”.

(a) Paragraph (7A) was inserted by S.I. 2011/1367.
(b) Article 23A was inserted by S.I. 2015/806.
(3) In paragraph (2), after sub-paragraph (d)(ii) insert—

“(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)(iiia) 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.”.
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 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 applicants for the restoration of an entry which was removed from the Register by a direction given by the Fitness to Practise Committee.

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 that 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 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.
Public business

Consultation: draft guidance on evidence of English language skills

Purpose
To provide the Council with the proposed consultation on draft guidance on evidence of English language skills

Recommendations
The Council is asked to agree the content of the consultation on draft guidance on evidence of English language skills.

1. Introduction
1.1 Article 23A of the Pharmacy Order requires the GPhC to consult on and publish guidance about
   • the evidence, information or documents that an applicant must 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 and
   • the process by which the Registrar is to determine whether he is satisfied that the applicant has the necessary knowledge of English.

1.2 These proposals have been developed with input from Council members over the past few months. The Council is now asked to approve the consultation document on draft guidance on evidence of English language skills. It is proposed that the Council will consider the draft consultation report and the final guidance in April 2016.

1.3 The draft guidance on evidence of English language skills is set out in the draft consultation document at appendix 1.
2. **Equality and diversity implications**

2.1 An equality assessment of the draft guidance will be published on the GPhC website during the consultation. Any further equality and diversity implications raised in responses will be covered in the consultation report.

3. **Communications**

3.1 The consultation will be published on the GPhC’s website. It will also be sent to a wide range of stakeholders and communicated to the pharmacy media. The consultation will run for 12 weeks and respondents will be able to respond online, by email or by post.

4. **Resource implications**

4.1 The launch and conduct of the consultation can be covered within existing resources.

5. **Risk implications**

5.1 Failure to consult appropriately on the proposed draft guidance would mean that the GPhC would not be complying with its statutory duties.

6. **Monitoring and review**

6.1 The impact of the guidance will initially be monitored through the consultation process and subsequently through performance monitoring reports submitted to the GPhC’s Council and published on our website.

6.2 The outcome of the consultation process is scheduled to be reported to the Council in April 2016, when it is anticipated that the Council will approve the guidance for publication.

6.3 Review of the guidance will be informed by performance monitoring reports and by any equality and diversity implications identified during this monitoring process.

**Recommendations**

The Council is asked to agree the content of the consultation on draft guidance on evidence of English language skills.

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20 August 2015
DRAFT

Consultation on draft guidance on evidence of English language skills.

September 2015
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The deadline for responding to this consultation is XXday XX December 2015.
Consultation on draft guidance on evidence of English language skills

1. Overview

The GPhC is consulting until **xxday xx December 2015** 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 (see art 23A, Pharmacy Order 2010, inserted by the Health Care and Associated Professions (Knowledge of English) Order 2015)\(^1\).

Alongside this consultation we are also consulting 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 consultation on the draft amendment to rules can be found here [link](http://www.legislation.gov.uk/uksi/2015/806/pdfs/uksi_20150806_en.pdf).

2. The consultation process

The Council has considered carefully a range of information and evidence as part of its development of this consultation on draft guidance. However, we wish to test our thinking and the Council wants to make the best possible decisions when it meets to consider approving the guidance. We need help from those with information and views, to test both our overall approach to the guidance as well as the specific proposals about the evidence we will require from pharmacy professionals to demonstrate that they have the necessary knowledge of English for safe and effective practice and the potential impact or benefits of these proposals. 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 **xxday xx 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, employers as well as patients’ representative bodies. We hope they will review this consultation and consider responding.

Further copies of this document are available to download from our website [Link] or you can contact us if you would like us to send you a copy of the document in an alternative format (for example in a larger font or in an alternative language).

**How to respond**

You can respond to this consultation in a number of different ways.

You can fill in the questionnaire at the end of this document or go to our website and fill in an online version there.

[<Link>](#)

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

**email**  [consultations@pharmacyregulation.org](mailto:consultations@pharmacyregulation.org) with the subject ‘English language consultation’

**address**  English language consultation response,
Regulatory Development Team,
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](mailto:feedback@pharmacyregulation.org)
or

**address**

English language consultation process  
Governance team  
General Pharmaceutical Council,  
25 Canada Square,  
London E14 5LQ

Please do not send consultation responses to this address.

**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](http://www.pharmacyregulation.org)

The Council is scheduled to consider approving the guidance at its meeting in April 2016 and the guidance would then be published once the parliamentary processes amending our Registration and Fitness to Practise rules had been completed.
3. 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 members of the public and, in particular, those members of the public who use or need the services of pharmacy professionals or services provided by a registered pharmacy.

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 principal functions include:

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

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 to 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’. This guidance on evidence and process has been drafted to comply with article 23A of the Pharmacy Order 2010.

The full text of the proposed guidance on evidence and process can be found in appendix 1.
4. Knowledge of English

4.1 The Health Care and Associated Professions (Knowledge of English) Order (S.I. 2015/806) (The Knowledge of English Order) was made in March 2015. The relevant provisions in it will come into force via a commencement order and will amend the Pharmacy Order to strengthen the GPhC’s powers to introduce fair and proportionate language controls.

4.2 The aim of these legislative changes is to improve public protection by making sure that only pharmacy professionals who have a sufficient knowledge of the English language for safe and effective pharmacy practice are eligible to register and work in Great Britain (GB).

4.3 The requirement to have the necessary knowledge of English for safe and effective practice applies to all applicants and registrants including those qualified in the European Economic Area (EEA) and Switzerland.

4.4 Article 23A of the Pharmacy Order requires the GPhC to consult on and publish guidance about
- the evidence, information or documents that an applicant must 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 and
- the process by which the Registrar is to determine whether he is satisfied that the applicant has the necessary knowledge of English.

4.5 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.

4.6 The Knowledge of English Order also 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.

4.7 The proposals set out in this consultation document are not designed to replace the important role that employers must continue to play in checking that the pharmacy professionals they employ have the necessary knowledge of English to practise safely and effectively in the role they have been employed to do.

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2 Article 23A of the Pharmacy Order is introduced by the Knowledge of English Order
5. The Guidance on evidence of English language skills.

Currently the only applicants who are required to provide evidence of their knowledge of the English language are non-EEA qualified pharmacists. They do this by providing us with evidence that they have passed the academic version of the International English Language Testing System (IELTS)\(^3\) test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking, at one sitting of the test.

The IELTS test certificate showing these scores must be provided as part of the non-EEA qualified pharmacist’s application for the Overseas Pharmacists Assessment Programme (OSPAP)\(^4\).

**Criteria for assessing language evidence**

Based on our experience of having used the IELTS test to demonstrate English language competence for non-EEA qualified pharmacist applicants we are proposing that all applicants must also demonstrate their competence in the English language in the four areas of:

- Reading
- Writing
- Listening and
- Speaking in English.

We are also proposing that any evidence provided must

- be recent, objective, independent and robust;
- clearly demonstrate that the applicant can read, write and communicate with patients, pharmacy service users, relatives and healthcare professionals in English; and
- be readily verifiable by us.

**Question 1**

Do you agree that these proposed criteria will provide the Registrar with adequate assurance that an applicant or registrant has the necessary knowledge of English for the safe and effective practice of pharmacy?

\(^3\) [http://www.ielts.org/](http://www.ielts.org/)

\(^4\) [http://www.pharmacyregulation.org/sites/default/files/international_information_pack_0315.pdf](http://www.pharmacyregulation.org/sites/default/files/international_information_pack_0315.pdf)
Types of evidence we will accept to demonstrate knowledge of English

UK qualified applicants

We are proposing 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\(^5\), and
- provided documentary evidence of these qualifications with their application for registration

would not normally be required to provide additional evidence of their English language competence to satisfy the Registrar that they have the necessary knowledge of English for safe and effective practice.

Question 2

Do you think that our proposals for UK qualified applicants are clear?

Non-UK qualified applicants

It is important that our proposals are fair and proportionate and to encourage consistency, we have looked at the guidance published last year by the General Medical Council in relation to both their International Medical Graduates and European qualified doctors.

The draft guidance therefore proposes that all non-UK qualified applicants can provide the same types of evidence to demonstrate their knowledge of English, irrespective of whether they qualified in

- an EEA country or Switzerland or
- a non-EEA country

The three types of evidence we are proposing to accept as evidence of English language competence are:

- Documentary evidence of having achieved the required scores in the IELTS test

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\(^5\) For the registration criteria for pharmacists please see http://www.pharmacyregulation.org/sites/default/files/Registration\%20criteria\%20for\%20pharmacists\%20September\%202012_0.pdf
For the registration criteria for pharmacy technicians please see http://www.pharmacyregulation.org/sites/default/files/Registration\%20criteria\%20for\%20pharmacy\%20technicians\%20Dec\%202013.pdf
• Documentary 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\(^6\).

• Documentary evidence of recent practice of at least 2 years in a country where English is the first and native language.

**Question 3**

*Do you agree that all non-UK qualified applicants should be required to provide the same type of evidence as specified under type 1, 2 or 3 in the guidance to demonstrate their knowledge of the English language?*

This proposal will result in a change to the evidence that we would accept from non-EEA qualified pharmacists to demonstrate that they have the necessary knowledge of the English language.

Currently these applicants are required to provide evidence of having recently\(^7\) passed the academic version of International English Language testing System (IELTS)\(^8\) test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking, at one sitting of the test. An IELTS test certificate showing that the applicant has achieved the required score must be submitted together with the application for eligibility to start the Overseas Pharmacists Assessment Programme (OSPAP). This requirement is applied irrespective of whether the non-EEA qualified applicant completed a pharmacist’s qualification taught and examined solely in English or worked in a country where English is the first and native language (for example in Australia or New Zealand).

The guidance proposes that non-EEA qualified pharmacists, like all other non-UK qualified applicants can, as an alternative, provide evidence of having a pharmacy degree taught and examined solely in English or documentary evidence of practice in a country where English is the first and native language to demonstrate that they have the necessary knowledge of English.

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\(^6\) First and native language is not the same as official language. The list of countries we accept is modelled on the UK Border Agency’s list of ‘majority English speaking countries’ plus Ireland (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/340583/English_language_v11.0_EXT.pdf).

\(^7\) When we refer to ‘recent’ we mean evidence relating to English language competency that is less than 2 years old at the point of making an application to the GPhC.

\(^8\) See http://www.ielts.org/ for further details about the IELTS test.
Question 4

Do you agree that non-EEA qualified pharmacists applying for the OSPAP should be able to demonstrate their knowledge of the English language by providing either type 2 or 3 evidence as specified in the guidance?

This would be instead of requiring all such applicants to provide evidence that they have passed the academic version of the IELTS test and achieve the required scores in one sitting.

We are also proposing that the same type of evidence of English language competence would be required irrespective of whether the applicant wishes to register as a pharmacist or pharmacy technician. This would mean that where relevant a non-UK qualified pharmacy professional wishing to register as a pharmacy technician would be required to pass the academic version of IELTS with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking, at one sitting of the test.

Question 5

Do you agree that, where relevant, non-UK qualified pharmacy technicians will be required to achieve the same scores in the academic version of the IELTS test as non-UK qualified pharmacists?

When to provide evidence of knowledge of English for first registration

An applicant for registration will need to provide evidence, information or documents to show they have the necessary knowledge of English for the safe and effective practice of pharmacy before they can register. We have set out the process to be followed in the guidance.

We are not proposing changes to the process for registration for UK qualified applicants. Such applicants are already required to provide documentary evidence of having successfully completed the relevant UK qualifications as set out in the criteria for registration as a pharmacist\(^9\) or pharmacy technician\(^10\).

Again in the case of non-EEA qualified pharmacists we are not proposing changing when such applicants will need to provide evidence, information or documents to show they have the necessary knowledge of English. As at present, documentary evidence will need to be provided with the application to start the OSPAP.

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\(^9\) [http://www.pharmacyregulation.org/sites/default/files/Registration%20criteria%20for%20pharmacists%20September%202012%200.pdf](http://www.pharmacyregulation.org/sites/default/files/Registration%20criteria%20for%20pharmacists%20September%202012%200.pdf)

\(^10\) [http://www.pharmacyregulation.org/sites/default/files/Registration%20criteria%20for%20pharmacy%20technicians%20Dec%202013.pdf](http://www.pharmacyregulation.org/sites/default/files/Registration%20criteria%20for%20pharmacy%20technicians%20Dec%202013.pdf)
The process for EEA qualified applicants is set out in the Knowledge of English Order. A formal request for evidence of an applicant’s knowledge of English can only be made after the applicant’s qualification is recognised.

In relation to EEA qualified applicants assessed via the EU General System provisions\(^\text{11}\) where we decide that the applicant’s qualification does not meet our national qualification requirements for registration, the applicant is required to successfully complete a compensation measure before their qualification can be recognised by us. Under the Directive\(^\text{12}\) it is our responsibility, as the competent authority, to determine how the compensation measure is to be structured and the status of the applicant undertaking it. Implementing legislation in relation to EEA qualified pharmacists\(^\text{13}\) provides that if a compensation measure is required this should be a period of adaptation training with assessments. Our policy is to require the applicant to complete a period of supervised practice with assessment in full compliance with our pre-registration training requirements.

In our guidance we are proposing that EEA qualified pharmacists or pharmacy technicians assessed via the EU General System provisions first provide evidence of their knowledge of the English language before they begin any required compensation measure\(^\text{14}\). This is because we want to make sure that their English language competence meets our requirements before they start working in a supervised capacity with patients, carers, their families and other healthcare professionals.

**Question 6**

Do you agree that EEA qualified applicants, who are required to complete a compensation measure under the General System provisions, should be required to provide evidence of their knowledge of English before they can start to work in a supervised capacity?

**Renewal of registration**

The guidance proposes that registrants renewing their registration would be required to specify whether they had evidence to demonstrate that they have the necessary knowledge of English. Registrants would be required to provide documentary evidence if requested to do so by the Registrar.

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\(^\text{11}\) Articles 10 to 14 of Directive 2005/36/EC on the recognition of professional qualifications

\(^\text{12}\) Article 3(1)(e) of Directive 2005/36/EC on the recognition of professional qualifications


\(^\text{14}\) The process outlined for General System applicants is dependent on the final government legislation and as such may be subject to change
Question 7

Do you agree with the proposal that, at renewal, registrants would be required to:

- specify whether they had evidence to demonstrate their knowledge of the English language and
- provide this if requested to do so by the Registrar?

Returning to the register

The guidance proposes a number of criteria which we would consider when determining whether a pharmacy professional needs to provide further evidence to demonstrate that they have the necessary knowledge of English. This is not an exhaustive list but the criteria we are proposing to consider include:

- The length of time since the applicant last practised in GB
- Whether they had practised elsewhere or continued to live in GB whilst off the register
- Whether they had previously demonstrated English language competence with their initial application for registration
- The length of time the applicant was registered and practising in GB
- Other information as may be relevant, for example whether concerns were raised about the applicant’s English language competence while previously registered.

Question 8

Do you agree with our approach to requesting further evidence of knowledge of English before we return an applicant to the register?

Concerns about language competence

In the guidance we are proposing that where we receive an allegation or have concerns that a registrant may not have the necessary knowledge of English, we can require the registrant to undertake the academic level IELTS test and achieve an overall score of at least 7 with no score less than 7 in each of the four areas of reading, writing, listening and speaking, at one sitting of the test.
Question 9

Do you agree that where there is an allegation or concern about a registrant’s knowledge of English the registrant can be required to undertake the academic version of the IELTS test and achieve the required scores in one sitting?

Response to the consultation on draft guidance on evidence of English language competence for the General Pharmaceutical Council

How to respond

The consultation asks a series of questions, which are listed below. You can fill in this questionnaire or go to our website and fill in an online version there.

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

email  consultations@pharmacyregulation.org with the subject ‘English language consultation’

address  English language consultation response,
          Regulatory Development Team,
          General Pharmaceutical Council,
          25 Canada Square,
          London E14 5LQ

If any of your answers take up more than the space we have allowed, you can attach extra pages if you want. Please indicate which questions any extra pages apply to.

Responses must be received by xxday xx December 2015

How we will use your response

Your response to this consultation will be used to help us make decisions on our guidance. 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 guidance on evidence of English language competence for 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.

☐ please remove my name from the published response

Please tell us if you have concerns with 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/or organisations and enables 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
Section A - Responding as an individual

Please tell us your:
name:______________________________________________________________________________
address:___________________________________________________________________________
_________________________________________________________________________________
email:____________________________________________________________________________

Where do you live?
☐ England
☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other (please give details)

Are you responding as:
☐ A pharmacy professional – Please go to section A1
☐ A member of the public
☐ Other (please give details)

Section A1 - Pharmacy professionals

Are you:
☐ A pharmacist
☐ A pharmacy technician

Please choose the option below which best describes the area you mainly work in:
☐ Community pharmacy
☐ Hospital pharmacy
☐ Primary care organisation
☐ Pharmacy education and training
☐ Pharmaceutical industry
☐ Other (please give details)

If you work in community pharmacy, are you:
☐ A pharmacy owner
☐ An employee
☐ A self-employed locum
Section B: Responding on behalf of an organisation

Please tell us your:

name:------------------------------------------------------------------------------------------------------------------

job title:------------------------------------------------------------------------------------------------------------------

organisation:------------------------------------------------------------------------------------------------------------------

address:------------------------------------------------------------------------------------------------------------------

email:------------------------------------------------------------------------------------------------------------------

a contact name for enquiries:------------------------------------------------------------------------------------------------------------------

contact phone number:------------------------------------------------------------------------------------------------------------------

Is your organisation a:

☐ Pharmacy organisation

☐ Non-pharmacy organisation

Please choose an option below which best describes your organisation:

☐ Body/organisation representing professionals

☐ Body/organisation representing patients/the public

☐ Body/organisation representing trade/industry

☐ Community pharmacy

☐ Corporate multiple

☐ Independent

☐ NHS organisation/group

☐ Research, education and/or training organisation

☐ Government department/organisation

☐ Regulatory body

☐ Other (please give details)
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 guidance.

1. Do you agree that these proposed criteria will provide the Registrar with adequate assurance that an applicant or registrant has the necessary knowledge of English for the safe and effective practice of pharmacy?

   (see page xxxx of the consultation document)

   □ Yes
   □ No
   □ Don’t know

   Do you have any further comments in response to question 1?

2. Do you think that our proposals for UK qualified applicants are clear?

   (see page xxxx of the consultation document)

   □ Yes
   □ No
   □ Don’t know

   Do you have any further comments in response to question 2?
3. Do you agree that all non-UK qualified applicants should be required to provide the same type of evidence as specified under type 1, 2 or 3 in the guidance to demonstrate their knowledge of the English language?

(see page xxxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 3?


4. Do you agree that non-EEA qualified pharmacists applying for the OSPAP should be able to demonstrate their knowledge of the English language by providing either type 2 or 3 evidence as specified in the guidance?

This would be instead of requiring all such applicants to provide evidence that they have passed the academic version of the IELTS test and achieve the required scores in one sitting.

(see page xxxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 4?
5. Do you agree that, where relevant, non-UK qualified pharmacy technicians will be required to achieve the same scores in the academic version of the IELTS test as non-UK qualified pharmacists?

(see page xxxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 5?


6. Do you agree that EEA qualified applicants, who are required to complete a compensation measure under the General System provisions, should be required to provide evidence of their knowledge of English before they can start to work in a supervised capacity?

(see page xxxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 6?


7. Do you agree with the proposal that, at renewal, registrants would be required to:

   • specify whether they had evidence to demonstrate their knowledge of the English language and

   • provide this if requested to do so by the Registrar?

(see page xxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 7?


8. Do you agree with our approach to requesting further evidence of knowledge of English before we return applicants to the register?

(see page xxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 8?


9. Do you agree that where there is an allegation or concern about a registrant’s knowledge of English the registrant can be required to undertake the academic version of the IELTS test and achieve the required scores in one sitting?

(see page xxx of the consultation document)

☐ Yes
☐ No
☐ Don’t know

Do you have any further comments in response to question 9?
### 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

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<th>Other</th>
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</table>
What is your age?
Please tick one box
- 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 orientation?
Please tick one box
- heterosexual
- lesbian or gay
- bisexual
- other

What is your religion?
Please tick one box
- None
- Christian
- Buddhist
- Hindu
- Jewish
- Muslim
- Sikh
- Other (please give more information in the box below)

Do you consider that you have a disability?
Please tick one box
- Yes
- No
Appendix 1

Evidence of English Language skills: Ensuring pharmacy professionals have the necessary knowledge of English to practise safely in Great Britain.

Introduction

1. It has been a long established requirement of professional ethics that healthcare professionals should have sufficient English language competence for safe and effective practice. The General Pharmaceutical Council’s (GPhC’s) Standards of Conduct, Ethics and Performance \(^{15}\) requires all registered pharmacy professionals to communicate effectively with patients and pharmacy service users and to work in partnership with them and other healthcare professionals to manage their treatment and care. If a registrant does not have the necessary knowledge of English there is a risk that they may not be able to act in the best interests of patients which could compromise patient safety and lead to a fitness to practise investigation.

2. The Health Care and Associated Professions (Knowledge of English) Order 2015 \(^{16}\) amends the Pharmacy Order and makes it a legal requirement for all registrants and applicants to have the necessary knowledge of English for safe and effective practice as a condition of registration with us. Previously, if a pharmacy professional was a national of the European Economic Area (EEA) or Switzerland, the Pharmacy Order prevented us from checking their English language skills before we registered them. We were only able to check the English language skills of non-EEA nationals who qualified outside the EEA.

3. The Knowledge of English Order improves public protection. It enables us to introduce fair and proportionate language controls that would apply to all registrants and applicants for registration irrespective of nationality or country of qualification and gives the Registrar powers to request evidence or information about a pharmacy professional’s knowledge of English in certain circumstances.

How this change will affect you

4. Article 23A of the Pharmacy Order 2010 \(^{17}\) requires the Council to publish guidance setting out the evidence, information or documents you must provide to show you have the necessary knowledge of English to practise safely in Great Britain and the process to be followed when making that determination.

5. The law and guidance applies to registrants and to all applicants seeking registration. It therefore applies:

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\(^{17}\) Article 23A of the Pharmacy Order was introduced by the Knowledge of English Order
• irrespective of whether you are applying to register as a pharmacist or pharmacy technician and
• irrespective of whether you qualified as a pharmacy professional:
  • in the United Kingdom (UK),
  • in another European Economic Area (EEA) member state or Switzerland, or
  • in a country outside of the UK, EEA or Switzerland.

6. The Registrar must take account of this guidance when deciding whether you have shown that you have the necessary knowledge of English. The Registrar can refuse to register you if you do not provide evidence of your knowledge of English or where the evidence you provide does not meet the criteria set out in this guidance.

Criteria for assessing language evidence

7. Our criteria for assessing evidence and information in relation to knowledge of English are set out below. The criteria reflect our objective of ensuring patient safety and provide us with adequate assurance that you have the necessary knowledge of English\(^\text{18}\) for the safe and effective practise as a pharmacy professional in Great Britain before we can register you.

8. The evidence you provide must demonstrate your competence in the four areas of:

• Reading
• Writing
• Listening and
• Speaking in English

and must:
• be recent, objective, independent and robust;
• clearly demonstrate that you can, read, write and communicate with patients, pharmacy service users, relatives and healthcare professionals in English; and
• be readily verifiable by us.

Types of evidence we will accept to demonstrate your knowledge of English

UK qualified applicants

9. If you are a UK qualified applicant wishing to register as a pharmacist having completed

• a GPhC accredited Master of Pharmacy degree from a university within the UK and
• pre-registration training and the registration assessment within the UK

you will in most cases automatically satisfy the Registrar that you meet the English language requirements for registration.

10. If you are a UK qualified applicant wishing to register as a pharmacy technician having completed

\(^{18}\) Article 3(1) and Article 20(1)(a)(iiia) and 2(a)(iiia) of the Pharmacy Order 2010 introduced by the Knowledge of English Order
• an approved knowledge and competency qualification in the UK while working under the supervision, direction or guidance of a registered pharmacist in Great Britain, Northern Ireland, the Channel Islands or the Isle of Man you will in most cases automatically satisfy the Registrar that you meet the English language requirements for registration.

Non-UK qualified applicants

11. There are different ways in which you may be able to demonstrate that you have the necessary knowledge of English to practise in Great Britain and this is reflected in the types of evidence we will accept.

12. We will review our English language evidence requirements on a regular basis to ensure they remain suitable. We will give full consideration to new sources of evidence that can provide the necessary assurance that you have the necessary knowledge of English.

13. However, based on our experience of assessing language evidence from international pharmacists qualified outside the EEA we have set out below the types of evidence we will accept as demonstrating that you have the necessary knowledge of English to practise as a pharmacy professional in GB.

Evidence type 1:

A recent\textsuperscript{19} pass of the academic version of International English Language testing System (IELTS)\textsuperscript{20} test with an overall score of at least 7 and with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.

14. We may accept IELTS test scores that are more than two years old if you can provide evidence to demonstrate that you have maintained your English language proficiency during that time. This can be for example if you have subsequently worked as a pharmacy professional in a country where English is the first and native language and at least 75% of your day to day interaction with patients, carers, their families and other healthcare professionals has been in English.

Evidence type 2:

A recent pharmacy qualification that has been taught and examined in English from a country (other than the UK) where English is the first and native language\textsuperscript{21} (e.g. Ireland, United States of America, Australia, New Zealand).

15. The entire course must have been taught and examined in English and at least 75% of any in-service training including clinical interaction, contact with patients, their carers and other healthcare professionals as part of that course of study must have been conducted in English.

\textsuperscript{19} When we refer to ‘recent’ we mean evidence relating to English language competency that is less than 2 years old at the point of making an application to the GPhC.

\textsuperscript{20} http://www.ielts.org/

\textsuperscript{21} First and native language is not the same as official language. The list of countries we accept is modelled on the UK Border Agency’s list of ‘majority English speaking countries’ plus Ireland (https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/340583/English_language_v11.0_EXT.pdf).
16. You will need to be able to show that your training provided you with the opportunity to
demonstrate your ability in reading, writing, listening and speaking in English.

Evidence type 3:
Recent practice for at least two years as a pharmacy professional in a country where English is the
first and native language.

17. You will be required to provide a detailed written reference from your employer(s) as to your
knowledge of English. As part of this reference an employer will be required to provide evidence
of how you have demonstrated your ability in the four areas of reading, writing, listening and
speaking in English.

18. If you were required to pass an English language test before being permitted to register and
practise as a pharmacy professional in another country where English is the first and native
language then you can provide evidence of having passed such an English language assessment.

When you need to provide us evidence of your knowledge of English for first registration
This section describes how and when you will need to provide evidence or information to show
whether you have the necessary knowledge of English for the safe and effective practice of
pharmacy in Great Britain, and the process we will follow. The process will depend on where you
qualified.

UK qualified applicants
19. If you are a UK qualified applicant the registration process has not changed since the English
language requirements were introduced. As before you will need to submit documentary
evidence of having successfully completed the relevant UK qualifications as set out in the criteria
for registration as a pharmacist or pharmacy technician together with your application for
registration. You must provide the evidence in the form and manner described in the
registration application form and supporting guidance. You will not normally be required to
provide further evidence of your English language ability.

20. Pharmacist applicants who had submitted a pre-registration training plan where they requested
to complete up to 13 weeks of their pre-registration training placement in another European
member state in accordance with the pre-registration training scheme and then passed the
GPhC registration assessment will also not normally be required to provide additional evidence
of their language ability with their application for registration.

Non-UK qualified applicants
21. If you are a non-UK qualified applicant, the process for providing evidence to demonstrate your
knowledge of English will depend on whether you qualified

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22 https://www.pharmacyregulation.org/sites/default/files/Registration%20criteria%20for%20pharmacists%20September%202012_0.pdf
23 https://www.pharmacyregulation.org/sites/default/files/Registration%20criteria%20for%20pharmacy%20technicians%20Dec%202013.pdf
in a country outside of the UK, EEA or Switzerland. If this applies you will need to follow the process described under non-EEA qualified applicants below.

in the EEA or Switzerland and are covered by the provisions in Directive 2005/36/EC on the Recognition of Professional Qualifications (the Directive)⁵. If this applies you will need to follow the process described under EEA qualified applicants below.

22. Non-EEA qualified applicants

22.1 If you are a non-EEA qualified pharmacist you will need to provide evidence to demonstrate your knowledge of English as part of your application for eligibility to start the Overseas Pharmacists Assessment Programme (OSPAP)⁶.

22.2 If you are unable to provide evidence to satisfy the criteria under either the primary pharmacy qualification or recent practice as a pharmacist in a country where English is the first and native language you will be required to provide evidence of your English language proficiency by achieving the required scores in the academic version of the IELTS in one sitting of the test.

22.3 If you are a non-EEA qualified pharmacy professional and wish to register as a pharmacy technician, because you will first have to complete the same requirements as a UK qualified applicant described in paragraph 10, you will not normally be required to provide additional evidence of your language ability with your application for registration. As at present you will need to submit documentary evidence of having successfully met the criteria for registration as a pharmacy technician together with your application for registration. You must provide the evidence in the form and manner described in the registration application form and supporting guidance.

22.4 However if a situation arises during the registration process where the applicant requires the services of a translator or another person in order to communicate in English with us we will review the evidence that has already been provided. In these cases we are likely to request further evidence of the applicant’s knowledge of English before granting registration.

23. EEA qualified applicants

23.1 If you are an EEA qualified pharmacist you are first required to make an application for recognition of your qualification. You are not required to provide evidence to show your knowledge of English when you make this application for recognition but you can do so if you wish.

23.2 If we determine that your pharmacist qualification meets the requirements for automatic recognition under the Directive⁷, we will inform you that we have recognised your qualification.

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⁶ http://www.pharmacyregulation.org/education/pharmacist/overseas-pharmacists-assessment-programme

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23.3 Where you had supplied evidence of your English language competence with your application for recognition and the Registrar determines that the evidence submitted meets our criteria and is described under types of evidence above, we will not normally request further evidence or information from you, and you can proceed to complete your application for registration.

23.4 Where

- you did not provide evidence to show your knowledge of English with your application for recognition or
- you did provide evidence but this does not satisfy the Registrar as to your English language competence,

we will still recognise your qualification, provided that this meets our requirements. We will write to you informing you of this and ask you to provide evidence of your language competence before you can progress on to registration. If you do not provide evidence of your knowledge of English with your initial application, this formal request for evidence cannot be made until we have recognised your qualification.

23.5 If you are an EEA qualified pharmacist or pharmacy technician and your application is being assessed via the EU General System provisions we will ask you to provide evidence of your English language competence before we authorise you to begin any required compensation measure. This is because we want to make sure that your English language competence meets our requirements before you start working in a supervised capacity with patients, carers, their families and other healthcare professionals.

23.6 If the Registrar is still not satisfied as to your English language competence after you have provided further evidence or information, or if you are unable to provide any evidence, we will ask you to pass the academic version of the IELTS test and achieve the required scores in one sitting before we can register you or before you can start the compensation measure where relevant.

**Renewal of registration**

24. In an application for renewal you will be required to specify whether you have evidence, information or documents demonstrating that you have the necessary knowledge of English. You will be required to provide this evidence if requested to do so by the Registrar.

**Returning to the register**

25. In cases where your registration has lapsed or you have voluntarily removed yourself from the register you may apply to the Registrar to return to the register and restore your entry. Some pharmacy professionals apply to return to the register soon after their registration has lapsed.

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27 For automatic recognition your qualification must be listed in Annex V 5.6.2 and comply with the minimum training requirements set out in Article 44 or you must be able to benefit from the acquired rights provisions set out in Article 23 of Directive 2005/36/EC.

28 Articles 10 to 14 of Directive 2005/36/EC.
while others do so after having been off the register for a more significant period of time for example after having spent time practising abroad or when returning to practise after a career break.

26. If you are returning to the register we will consider the following criteria to determine whether you have shown that you have the necessary knowledge of English:

- The length of time since you last practised in GB
- Whether you had practised elsewhere or continued to live in GB whilst off the register
- Whether you had previously demonstrated English language competence at your initial registration
- The length of time you were registered and practising in GB
- Other information as may be relevant for example whether concerns were raised about your English language competence while previously registered.

27. This is not an exhaustive list but gives an indication of matters we will take into account in determining whether to request further evidence of your knowledge of English before returning you to the register.

**Fees**

28. If you are requested to pass the academic version of the IELTS test and achieve the required scores in one sitting before applying for registration or restoration, you must pay the fee for taking the IELTS test yourself.

**Rights of appeal**

29. Article 39 of the Pharmacy Order sets out that you have a right of appeal to the Appeals Committee where the Registrar makes the decision that he is not satisfied that you have the necessary knowledge of English and requires you to take an examination or assessment (the IELTS test).

**If a concern about language competence is raised whilst a pharmacist or pharmacy technician is on the register.**

30. Under article 51(1)(ca) of the Pharmacy Order, your fitness to practise may be considered to be impaired on the basis that you do not have the necessary knowledge of English. If we receive an allegation or have concerns ourselves that you do not have the necessary knowledge of English and as a result your fitness to practise may be impaired then this will be treated as an allegation that will be dealt with via the fitness to practise process. Such cases will be dealt with in a similar way to any other allegation of impaired fitness to practise. If you are subject to such an allegation or concern the Registrar, Investigating Committee or Fitness to Practise Committee can require you to be assessed as to your knowledge of English. If this happens you will be required to undertake the academic version of the IELTS test and achieve an overall score of at least 7 with no score less than 7 in each of the four areas of reading, writing, listening and speaking at one sitting of the test.
Next steps for CPD call and review

Purpose
To outline the next steps the organisation will take to improve efficiency and effectiveness of the continuing professional development (CPD) call and review process.

Recommendations
The Council is asked to note the activities for planned improvements to the Call and Review process. These activities are:

- Modify and simplify the recording requirements for CPD entries.
- Improve the online recording tool to make it more accessible and recording simpler.
- Consult upon changes to the CPD framework including introducing a random sampling approach.
- Communicate to all registrants the continued requirement to undertake and record CPD activities under the current requirements.

The Council is also asked to approve:

- Rescheduling the commencement of the next cycle for CPD until these changes have been implemented.

1. Introduction

1.1 CPD has been mandatory for all pharmacy professionals since 2009. Since then every eligible registrant has been called to submit their CPD records for review.

1.2 As of 31 July 2015, 68,206 registrants have had their records reviewed. This is not a complete sample as some registrants have applied for extensions (for reasons such as maternity leave) meaning the review process for all eligible registrants will not complete until Spring 2016.
1.3 The issuing of the final call marks the end of the first 5 year cycle of mandatory CPD for pharmacy professionals. It is an appropriate time to consider carefully the next steps we will take in our work to assure CPD compliance before new arrangements for continuing fitness to practise are introduced from 2018.

1.4 This paper sets out the learning from a number of different areas and the resulting steps that will be taken to improve assurance of CPD compliance.

2. **Summary of our current approach**

2.1 All registrants are required to undertake and record CPD activities on a continuous basis either directly into an online recording tool (known as uptodate.org) or on paper.

2.2 In each year of a five year cycle, we randomly select approximately 20% of the eligible registrant population and give six weeks’ notice that CPD records must be submitted to us.

2.3 Registrants submit their records to us in the online recording tool or via paper (in which case we arrange for transcription into the online recording tool).

2.4 If a registrant does not submit their CPD records on time, and they have not gained an approved extension, they are reminded twice, issued a notice of intention to remove and finally a notice of removal from the register. Then they are administratively removed from the register.

2.5 If a registrant submits records to us but they fall short of our requirements they are entered into remediation. They are given further opportunities to meet requirements. If they do not meet requirements after multiple opportunities, they are issued with a notice of intention to remove and finally a notice of removal from the register. Then they are administratively removed from the register.

2.6 In some cases we make referrals to our fitness to practise team as a result of information that comes to light from the CPD call and review.

2.7 If a registrant meets our requirements for CPD they are issued a feedback report.

2.8 Registrants may be called again at any time, however, most registrants will not be called until another five years has passed.

3. **Summary outcomes from five years of call and review**

3.1 The table below summarises the outcomes we have reached for the 68,206 reviews that have been completed.
Total number of registrant CPD reviews undertaken | 68,206 (100%)
---|---
Number of registrants who failed to submit any records and were removed for non-compliance | 202 (0.3%)
Number of registrants meeting requirements at first attempt | 67249 (98.6%)
Number of registrants entered into remediation | 752 (1.1%)
Number of registrants meeting requirements after remediation | 744
Total accumulated compliance 67,996 (99.7%)
Number of registrants failing to meet requirements after remediation* | 3 (less than 0.01%)

*At the time of writing there are three registrants still in process of receiving notices and two registrants in unrelated fitness to practise proceedings which may impact upon this final figure potentially bringing the percentage to 0.01.

3.2 It should be noted that there have been no referrals into fitness to practise processes which have resulted in any action being taken on a registrant.

3.3 It should also be noted that a number of registrants voluntarily remove themselves from the register after being called to submit CPD records. There is no data recorded which definitively links a voluntary removal to the call and review process therefore we cannot determine if the call was the trigger. In future, we will try to capture this information; however, it may never be a complete data set as some former registrants will choose not to explain their reasons for leaving the register.

4. Learning from the CPD review

4.1 The review conducted by IFF Research Ltd. highlighted the following potential improvements to how we undertake CPD call and review:

- enhance the ease of use of the online recording tool to encourage good practice.
- amend the five yearly call cycle to an annual cycle so that registrants record their CPD more frequently.
- randomly sample the register to encourage registrants to record their CPD more frequently.
- simplify and reduce the amount of recorded content we require.
• require registrants to record CPD that provides a greater focus – particularly for those in patient facing roles – on the benefits to patients and service users.

5. Learning from the operational review

5.1 The operational review of the call and review process, conducted as an internal exercise, has highlighted potential improvements and cost savings including:

• enhanced record submission and management reporting that is less reliant on manual processing.
• shifting to a random sampling approach of the register.
• making paper submission of CPD records by exception only for individuals with additional needs.
• automating the CPD submission process to prevent an insufficient number of CPD entries being submitted (which is the most common reason for entry into remediation).

6. Sampling

6.1 Sampling is an efficient and effective method that requires only a proportion of the register to be assessed for CPD in any one year. A random sampling method is most appropriate when the population being sampled consists of similar individuals and ensures that each member has an equal chance of their CPD being selected for assessment. Sampling is the method used by the majority of health regulators and so work has been undertaken to consider options for moving to a sampling approach. Consideration has been given to a number of factors that could influence a proposed sampling method, including:

• the statistical relevance of the sample to provide assurance of compliance rates of the whole register.
• the perception from registrants toward the likelihood of being selected for audit which drives, in some, recording of CPD.
• the regularity which with a registrant may be selected for audit.
• the experience of other health professional regulators.
• increasing the available time per audit of each selected Registrant.

6.2 It is apparent from this initial work that moving to a random sample of 2.5% of the register each year would:

• give more than sufficient statistical assurance of the compliance rates of the register.
• mean registrants are likely to know someone who has been selected.
• make registrants eligible for audit more regularly than once in five years (though we would expect a registrant once selected would not be eligible for audit the following year unless problems arose in the submission).
• be consistent with the approach of other regulators.
• be compliant with equalities legislation and robust in the face of challenge.
• provide the opportunity to give a greater level of feedback to registrants selected for audit.

6.3 Further work is required to understand the implications of this change and therefore a consultation will be conducted on the approach. The draft consultation will come to a future meeting for approval by Council.

6.4 Until the Council agrees the outcomes of any consultation the current requirements will remain as they are and registrants will be expected to comply with the current CPD framework.

7. Transitioning to a new approach for CPD and to assure continuing fitness to practise

7.1 As part of the transition to a new framework to assure continuing fitness to practise, it was agreed by Council that where possible there would be incremental changes made to the current CPD requirements.

7.2 With the intention to implement new arrangements for continuing fitness to practise in 2018, it would mean that a five year cycle of call and review commencing now would be divided by “current” and “future” requirements.

7.3 Emerging findings from testing and from the now complete CPD review suggest that we are shortly to be in a position to make positive changes that would be consistent across the current and future requirements.

7.4 Therefore, as part of the transition, Council is asked to approve that the next call of records for review is rescheduled until consultation and improvement work is completed.

8. Equality and diversity implications

8.1 Equality and diversity implications have been considered as part of the operational review. Specific consideration has been given to accessibility of recording of CPD using the current methods and how improvements can be made in future. In particular, consideration has been given to how paper recording of CPD can be reduced in number but still allow registrants with additional needs appropriate options to record their CPD in an accessible format.
8.2 Consultation will provide a further opportunity to analyse the equality and diversity implications of any changes.

9. Communications
9.1 Communication of the rescheduling of the next call is critical. The CPD review report indicates that recording is in many cases driven by the call for records submission. If there are no calls for a defined period of time, a group of registrants may choose to undertake but not record their CPD activities. Therefore communications around rescheduling the call must be careful to highlight the ongoing responsibility to record CPD and also make it clear that a call will be undertaken in future taking into account the last five years of practice.

9.2 A cohort of registrants from the last five year cycle are still to submit and will receive specific communications indicating the continued requirement to submit their CPD entries for review.

9.3 Communication channels will include routine methods, including mailings and Regulate.

10. Resource implications
10.1 Operational team time will be saved by rescheduling the commencement of the next cycle and can be re-invested in process and technical infrastructure improvements.

10.2 Policy team time has already been planned in the 2016-17 financial year to support a consultation on new requirements and will be subject to routine scrutiny through annual business planning processes.

10.3 Information technology and project management team time has already been allocated to developing a technical infrastructure suitable for piloting for the continuing fitness to practise framework in 2016-17. This will also be subject to routine scrutiny through annual business planning processes.

10.4 Potential cost savings identified by making these changes are significant in both the short and longer term. In the short term any shift to a smaller random sample will reduce the administration and resource costs of the CPD programme in proportion to the sample size selected, while presenting an opportunity to improve the effectiveness and proportionality of our current regulatory activity in terms of assessor oversight and feedback. In the longer term, changes to automated process infrastructure will result in administrative efficiencies.

11. Risk implications
11.1 The central risk is highlighted in the communication section of the report as registrant’s recording behaviour must not be negatively affected by rescheduling the next call. This risk is being partially mitigated by
communications activities, however, it should be recognised that many registrants are already only recording their CPD once every five years following a call so the activities outlined in this paper are intended to reduce risks overall.

11.2 The impact of any change to sample size will be carefully monitored to ensure our current high compliance levels with CPD requirements are maintained. We expect these changes will actually increase frequency of recording, ensuring more meaningful annual declarations by registrant that their CPD is up to date.

12. Monitoring and review

12.1 Changes to CPD policy will be managed within the strategy directorate business plan for 2015-16 and 2016-17. Reporting will be undertaken monthly, with Senior Leadership Group and Council approval sought for key decisions.

12.2 Changes to operational process will be managed within the operations directorate business plan for 2015-16 and 2016-17

Recommendations

The Council is asked to note the activities for planned improvements to the Call and Review process. These activities are:

- Modify and simplify the recording requirements for CPD entries.
- Improve the online recording tool to make it more accessible and recording simpler.
- Consult upon changes to the CPD framework including introducing a random sampling approach.
- Communicate to all registrants the continued requirement to undertake and record CPD activities under the current requirements.

The Council is also asked to approve the:

- Rescheduling the commencement of the next cycle for CPD until these changes have been implemented.

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19 August 2015
Public business

Chief Executive and Registrar's report

Purpose
To keep Council abreast of significant recent meetings and developments.

Recommendations
The Council is asked to note this paper.

1. Recent meetings
1.1 Listed in Appendix 1 is a non-exhaustive selection of significant meetings held during the two months since the last Council meeting.

1.2 Council members are reminded to liaise with the office before accepting external invitations to speak on behalf of the GPhC in order to minimise overlap and to ensure that they have the most up-to-date supporting material.

2. GPhC Annual report 2014-15
2.1 The GPhC Annual report 2014-15 was published in June. Key achievements for 2014-15 highlighted in the report include:

- progress made in developing the new inspection model;
- development of a framework for continuing fitness to practise;
- introduction of changes to the registration assessment from 2016; and
- improvements in our day-to-day operations.

2.2 The report also sets out our priorities for 2015/16 including:

- holding a conversation about what ‘patient-centred professionalism’ means in practice, and using this work when we review the standards of conduct, ethics and performance;
• working to produce new regulatory standards for the education and training of pharmacists and pharmacy technicians, which reflect public expectations and professional values; and
• improving the quality of our handling of fitness to practise cases, and the speed with which we deal with them.

3. **Registration assessment June 2015**
3.1 There were 2811 candidates who sat the GPhC’s Registration Assessment on 27th June 2014. 2077 candidates passed the exam which is an overall pass rate of 74%. 2621 candidates sat the assessment for the first time, 116 for the second time and 74 for the third time. The list of successful candidates is available on our website.

4. **Pharmacist prescriber survey**
4.1 On 18 August we launched a survey of all pharmacist prescribers to help us gain a better understanding of current prescribing practice.
4.2 We want to understand the extent to which pharmacists are prescribing, where prescribing takes place, the barriers and enablers to prescribing and the resources that pharmacist prescribers use.
4.3 We would also like to understand what guidance and support exists for pharmacist prescribers and prescribing practice and what further guidance or support may be helpful from the GPhC.
4.4 The survey is open until 7 October 2015.

5. **Continuing fitness to practise**
5.1 Testing of the GPhC’s draft continuing fitness to practise (CFtP) framework commenced in June and will conclude in September. Approximately 250 volunteers from a range of roles, settings and countries are now using an online tool to trial modified CPD recording, peer discussion, and using evidence from professional practice.
5.2 Analysis of the responses is ongoing and, along with evaluation surveys and interviews, will feed into a report for Council in December 2015 presenting findings and recommendations for the pilot phase in 2016-17.

6. **Memoranda of Understanding update**
6.1 The GPhC now has MOUs with 19 organisations across our regulatory remit in England, Scotland and Wales. The full list of organisations and MOU documents are available on the GPhC website: http://www.pharmacyregulation.org/about-us/who-we-work
6.2 One year on from signing the first MOUs, the GPhC carried out a review of the impact to date of these agreements, progress in implementing them and their emerging benefits.

6.3 From this review, we know that the MOUs foster better working relationships between the GPhC and a range of organisations, increase timely relevant information sharing and improve how pharmacies are inspected. Taken together, they support robust pharmacy inspection which helps to keep patients and the public safe, and, create the potential to reduce the burden of inspection.

6.4 We have also gained insight into how we can strengthen the effectiveness of all the agreements we hold. Consequently, we are revising some MOUs and strengthening the practical application of all through providing more comprehensive contact and referral information.

6.5 Over the next 12 months, with our MOU partners, we will ensure that regular contact is maintained, continue to develop joint programmes of work, and review effectiveness in terms of improving information sharing, reducing inspection activity, and contribution to patient safety.

7. **Consultation on GPhC investigating committee guidance**

7.1 A consultation on revised guidance for the investigating committee to use when deciding what outcome is appropriate in a fitness to practise case has been running from 2 July to 11 September. Good decision making: investigating committee meetings and outcomes guidance explains the role of the investigating committee and how it decides whether a case should be considered by the fitness to practise committee.

7.2 Following analysis of the consultation responses and engagement activities, revised guidance will be presented to Council for approval by the end of the year.

8. **Ministerial meeting**

8.1 On 15 July the Chair, along with colleagues from the RPS and various community pharmacy organisations, met with Rt Hon Alistair Burt MP, Minister of State for Community and Social Care. The Minister was keen to discuss opportunities for community pharmacy in primary care and understand how these services can best be delivered.

8.2 The meeting was constructive and reflected the collaborative spirit within pharmacy. The Minister has agreed to a further meeting with the Chair and Chief Executive.
9. **One Chance to Get it Right: One Year On**

9.1 A year ago the Leadership Alliance for the Care of Dying People (LACDP), of which the GPhC was a member, published One Chance to Get it Right which set out actions to improve care in the last days and hours of life.

9.2 On 13 August this year the Government published the *One Chance to Get it Right: One Year On Report* which shows the progress organisations have made against those commitments.

10. **Rebalancing update**

10.1 The Chair and Priya Warner, Head of Standards and Fitness to Practise Policy, attended the latest meeting of the Rebalancing Programme Board on 28 July. The minutes from this meeting, when published, will be available at: https://www.gov.uk/government/policy-advisory-groups/pharmacy-regulation-programme-board

**Recommendations**

The Council is asked to note this paper.

*Duncan Rudkin, Chief Executive and Registrar*

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20 August 2015
Appendix 1

List of meetings

Listed below is a non-exhaustive selection of significant meetings held during the two months since the last Council meeting. Initials are as follows: Nigel Clarke (NC), Duncan Rudkin (DR), Bernard Kelly (BK), Hugh Simpson (HS), Claire Bryce-Smith (CBS):

Chair (Nigel Clarke):

- Pharmacy and Public Health Forum
- Rebalancing Partners Forum Meeting (with DR and CBS)
- RPS Presidential Reception (with DR)
- Meeting with Rt Hon Alistair Burt MP (with other pharmacy organisations)
- Regulators Chairs’ Meeting
- Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board (June with DR, July with Priya Warner)
- Meeting with RPS English Board (with DR)

Staff:

- APTUK Annual Conference (DR – speaking)
- Pharmacy Health Education England Advisory Group (HEEAG) (DR)
- Pharmaceutical Care Awards (DR)
- RPS Presidential Reception (with NC)
- Rebalancing Partners Forum Meeting (with NC and CBS)
- Chief Executive, Professional Standards Authority - update meeting (DR)
- Law Commission Bill inter regulator forum (HS)
- Rebalancing Medicines Legislation and Pharmacy Regulation Programme Board (DR with NC)
- Task and Finish Group Meeting with Chief Pharmacists Wales (CBS)
- Meeting with Chief Pharmaceutical Officer, Scotland (DR)
- Pharmacist Education and Training Reforms Programme Board (HS)
- Chief Executives’ Steering Group (DR)
- Health and Social Care Regulatory Forum (HS)
- Meeting Chief Executive, RPS (DR)
- Meeting with Chief Pharmaceutical Officer, England (DR)
- General Secretary, Pharmacists’ Defence Association (CBS)
- Meeting with RPS English Board (DR with NC)
Public business

Professional Standards Authority performance review report 2014-15

Purpose
To provide Council with an update on the Professional Standards Authority (PSA) performance review process.

Recommendations
The Council is asked to note this paper.

1. Performance review 2014-15

1.1 The PSA performance review report for 2014-15, which contains the Authority’s reports on the performance of the nine health and social care professional regulators, was laid before Parliament on 25 June. The report is available here.

1.2 The PSA assessment is that the GPhC has met all but one of the Standards of Good Regulation. The GPhC did not meet the sixth Standard of Good Regulation for fitness to practise, which relates to the timely progression of cases through the fitness to practise process.

1.3 The GPhC met all the Standards of Good Regulation for Guidance and Standards; Education and Training; and Registration. The PSA highlighted a number of examples of how we demonstrated that we met the standards, including:

- Publishing guidance on preparing unlicensed medicines.
- Publishing findings of the registrant survey carried out in 2013.
- Developing plans for engaging with stakeholders on the review of the standards of conduct, ethics and performance and on the wider theme of professionalism.
- Progressing the development of our continuing fitness to practise framework.
• Improving registration processes by introducing an online portal for renewal of premises registration.

2. Sixth Standard of Regulation for fitness to practise

2.1 Although we did not meet this standard, the PSA acknowledged that the GPhC had improved performance by reducing the median length of time it takes to process cases from the initial receipt of complaint to the final fitness to practise hearing from 97 weeks in 2013-14 to 85 weeks in 2014-15.

2.2 The Authority also noted the following measures implemented in 2014-15 aimed at improving performance including:

• Introduction of a new case supervision framework in June 2014.
• Increase in the number of Investigating Committee meetings.
• Increase in the number of staff supervising and managing casework.

2.3 The PSA remains concerned about:

• The amount of time taken to progress through various stages of the fitness to practise process
• The increase in the number of cases over 52 weeks old
• The number of high court extensions to interim orders

2.4 Overall, the PSA considered the GPhC did not demonstrate that it deals with cases as quickly as possible across its entire caseload and as a result did not meet the standard.

3. Performance review 2015-16

3.1 The PSA recently held a consultation on proposals for a revised performance review process for 2015-16 onwards. The GPhC response to the consultation is available here.

3.2 Until the Authority responds to the consultation, we do not know what form the performance review process will take for 2015-16 and beyond. It is likely that the existing Standards for Good Regulation will remain unchanged, with the addition of a standard relating to risk.

4. Equality and diversity implications

4.1 There are no equality and diversity implications raised in this paper.

5. Communications

5.1 The PSA publishes the performance review report on its website.

5.2 We continue to publish updates on our performance across a range of issues through performance monitoring reports and corporate plan updates to Council.
6. **Resource implications**

6.1 From August 2015 the PSA will be funded by a levy imposed on all the health and social care regulators it oversees. The GPhC will be liable to pay £147,834 for the period 1/8/15-31/3/16. This has been included in the budget for 2015-16.

7. **Risk implications**

7.1 There are risks for the GPhC if it fails to respond adequately to recommendations made by the PSA.

7.2 The GPhC strategic plan sets out our commitment to making measurable progress to resolve concerns about the fitness to practise of pharmacists and pharmacy technicians more quickly.

7.3 We have effective monitoring procedures in place to ensure we are keeping track of, and monitoring progress with, PSA recommendations.

**Recommendations**

The Council is asked to note this paper.

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25 August 2015
Public business

Embedding learning from the Mid Staffordshire Public Inquiry

Purpose
To update Council on progress to embed learning from the Mid Staffordshire NHS Foundation Trust inquiry and recommendations in the Francis report.

Recommendations
The Council is asked to note this paper.

1. Introduction

1.1 In February 2013, Robert Francis published his report\(^1\) into the profound failings of care that occurred at Mid Staffordshire NHS Foundation Trust between 2005 and 2009.

1.2 Council had a number of discussions on the implications for pharmacy regulation and the wider healthcare context. While none of the recommendations were specifically addressed to the GPhC, Council’s view was that it was incumbent upon us to ensure we consider each of the major themes identified in the report and embed these in our corporate planning and policy development.

1.3 This approach, to identify what pharmacy and pharmacy regulation can learn from high profile failures in care and the subsequent reports, has been taken with the *Trusted to Care* report\(^2\) into care at Abertawe Bro Morgannwg University Health Board in Wales, as well as the inquiry into the Vale of Leven hospital in Scotland\(^3\).

2. Key themes for the GPhC

2.1 The key themes Council identified which were directly relevant to our work were:

\(^1\) [http://www.midstaffspublicinquiry.com](http://www.midstaffspublicinquiry.com)
\(^3\) [http://www.valeoflevenhospitalinquiry.org/](http://www.valeoflevenhospitalinquiry.org/)
i. Patient experience and patient voice
ii. Transparency (including data and information sharing)
iii. Candour
iv. Whistleblowing
v. Professionalism

1.1. We have since taken these themes into account as we have developed and implemented our policy and operational changes across standard setting, education, inspection and enforcement.

1.2. We have not attempted to provide a comprehensive report in this paper of everything we have done across these themes as this would replicate much of what is in our corporate reporting and repeat detail set out in specific Council Papers and workshop sessions. However, the examples set out below are intended to assure Council that we have adopted effectively the approach agreed of embedding the key themes into our work.

3. **Patient experience and patient voice**

3.1 In January 2015 we published a report of a survey on the public perception of the pharmacy profession and pharmacy services in Great Britain. The survey, carried out by Ipsos MORI, provides us with a better understanding of where the public considers seeking information about specific health services and explores the experiences of those who visit pharmacies and use pharmacy services.

3.2 We have continued to build patient and service user involvement throughout our policy development process. Most recently we have held focus groups and meetings with patients and the public across Great Britain to find out their expectations of pharmacy professionals today, as part of our discussion on patient-centred professionalism.

3.3 We have begun work to set up a patient advisory panel which would enable us to seek the views and experiences of members of the public more quickly and effectively and better enable their views to influence our regulatory work.

3.4 We have introduced a range of improvements to make sure we are dealing with concerns thoroughly and quickly, despite the significant increase in numbers. This includes having more staff work on fitness to practise concerns, and improving the online form on our website to make it easier for people to report a concern.

4. **Transparency (including data and information sharing)**

4.1 Council has already demonstrated a commitment to increased transparency in its work.
4.2 We are increasingly publishing information and data we hold. An example of this is the increasing amounts of information published about the registration assessment and the issues that this raises in relation to variable performance by students.

4.3 We have continued to operate as transparently as possible (given the current legislative framework) in relation to development of our approach to standard setting and development of our inspection model. We remain committed to publish inspection reports in future, subject to the passing of legislation.

4.4 GPhC has a range of memoranda of understanding (MoUs) agreed with other regulators and key stakeholder organisations. The MoUs were established as part of an overarching commitment to better regulation and reducing regulatory burden through:

- improving information sharing between organisations
- creating potential for reducing inspection activities in registered pharmacies
- making a positive contribution to patient safety.

4.5 Alongside reducing regulatory burden, the MoUs were established to make a positive contribution to patient safety and improve information sharing between organisations. This is critical, as one of the key risks identified by the Francis Inquiry was of regulators and organisations failing to share information and communicate feedback on risks and events appropriately. The MoUs that we have agreed with other key organisations help us to address this risk through engendering stronger relationships. As a result, many of the practical difficulties in sharing information have been overcome as:

- relevant contacts are already known or easily identified
- there is increased knowledge of each other’s remits, jurisdiction and areas of interest or concern
- we have a better understanding of each other’s regulatory models and processes.

4.6 The evidence gathered for our internal MoU review, in Spring 2015, has provided assurance that we are responding more effectively and efficiently to patient safety concerns. In particular, our work with other health related organisations in response to emerging issues, for example Healthcare at Home shows a more joined up and timely approach to identifying and addressing risks to patient safety than might otherwise have been the case.

5. **Candour**

5.1 In October 2014, along with seven of the other regulators of healthcare professionals, we signed a joint statement on the professional duty of
candour⁴, reflecting Council’s public commitment to promote candour by registrants.

5.2 We have promoted the duty of candour to our registrants, our students, and to patients, through our online channels and engagement activities to help ensure registrants know what this means and what we expect of them. Our focus has been on embedding the duty of candour into all of our standards and guidance.

5.3 As part of the review of our indicative sanctions guidance, we published a discussion paper: Supporting decision making in hearings⁵ which sought views on a range of issues our fitness to practise committees face including failures to be open and honest. We included a new section in the guidance, specifically drawing on learning from the Francis Report, to state that committees must consider sanctions at the upper end of the scale when cases involve failing to be candid, trying to cover up problems, encouraging others not to tell the truth or fostering a culture which does not encourage candour. The final version⁶ significantly strengthens Council’s position and guidance to the Fitness to Practise Committee.

6. Whistleblowing

6.1 Through our response to the Freedom to Speak Up review consultation⁷, we committed to using the learning from the recent reports and the inquiries into failures in care, and adopting the principles of this report across the work we do.

6.2 We have also highlighted this as an important theme in our review of standards for registered pharmacies.

7. Professionalism

7.1 Council has made clear it believes that it is the demonstration of professionalism by pharmacists and pharmacy technicians in their day-to-day work which make the most significant and positive contribution to quality improvements in pharmacy and in managing risks to patients.

7.2 We have attempted to raise the importance of professionalism and to stimulate discussion with the sector. This initiative was highlighted by our

⁴ http://www.pharmacyregulation.org/sites/default/files/joint_statement_on_the_professional_duty_of_candour.pdf


Chair at the Pharmacy Show in November 2014 when we launched our patient-centred professionalism review. We have continued to promote this theme in our corporate publications, in Regulate and in our consultations.

7.3 In April 2015, we launched our discussion paper ‘patient centred professionalism in pharmacy’ to have an honest and open conversation about what it means to be a pharmacy professional in the 21st century.

7.4 We heard from over 500 individuals and organisations. We will use what we heard to underpin and inform all our regulatory work, in particular the development of our standards of conduct, ethics and performance. We will also share our findings with others to inform their work too.

7.5 We were previously part of the ‘Leadership Alliance for the Care of Dying People’. As part of the follow up from this work, DH have launched the ‘One Chance to Get it Right - One Year On’ report\(^8\) which we contributed to. This covers the work we have done to embed candour, refers to our education standards review and to our patient-centred professionalism discussion.

7.6 We have embedded a joined up approach to standards development across education standards, professional standards and ‘system’ standards for registered pharmacies. There are effective links between emerging data trends from both professional and system regulation which we are addressing within our approach, policy and operational development for regulation of pharmacies.

8. **Equality and diversity implications**

8.1 Equality and diversity implications will be considered alongside any major policy initiative. For those requiring formal consultation we will continue to publish separate equality impact assessments.

9. **Communications**

9.1 Each piece of work has involved communication and engagement with relevant stakeholders, including patients and users of pharmacy services, registrants, employers, professional organisations and education and training providers.

10. **Resource implications**

10.1 Resource requirements will be incorporated into our corporate planning process and met within existing budgets.

11. **Risk implications**
11.1 Council previously highlighted concern that a failure to consider fully the learnings from the Mid Staffordshire public inquiry could contribute to outdated or ineffective policy development and regulatory practice. We have sought to mitigate this risk by considering and embedding the key themes set out previously and included in this paper.

12. **Monitoring and review**
12.1 This work has now been fully embedded into our strategic and corporate planning processes and ongoing work programme.

**Recommendations**

The Council is asked to note this paper.

*Hugh Simpson*

*Director of Strategy*

10 September 2015
Public business

Performance Monitoring Report

Purpose
To report to Council on operational and financial performance to the end of July 2015

Recommendations
The Council is asked to note and comment on the performance information presented at Appendix 1

1. Introduction
1.1 This paper reports on operational and financial performance to the end of July 2015.
1.2 The sections below provide an executive summary of key areas to note within the report.

2. Registration
2.1 Registrations of new Pharmacists and Pharmacy Technicians remain stable from month to month in line with the expected trends and are broadly in line with the budgeted figures.
2.2 A number of recurring, annual factors have increased the workload within the contact centre and reflects the increase in call volumes and the reduction in calls answered within 20 seconds.

3. Fitness to Practise (FtP)
3.1 Performance has been positive over this reporting period. There have been improvements in four out of the five performance standards. Of note is the performance improvement in the percentage of cases closed at FtPC within 24 months; this rose to 78% (21 cases), up from 42% (five cases) in the last report.
3.2 In both May and June, more cases were closed than received. In July, the highest number of concerns received in a month was recorded, at 182. As a result, the overall open caseload has risen by just 14.
3.3 Direction of travel in reducing the age profile of the open caseload continues to be positive. The open caseload is getting younger. The number of open cases over 12 months old has reduced to 151, from 162 cases in the last report.

3.4 In relation to case closures this reporting period, there has been a significant improvement in the number of cases closed at the FtP Committee and Stream 1 stages.

4. **Inspection**

4.1 Inspection productivity is improving, with the second highest number of routine inspections undertaken in July since the new approach to inspection began.

4.2 Whilst the number of pharmacies over the age of 48 months not inspected has increased, the rate of growth has slowed slightly. This follows the increased focus of inspectors in this category. From our monitoring to date, there is no evidence that those pharmacies that have waited the longest to be inspected demonstrate poorer performance.

5. **Human Resources**

5.1 The overall stability rate is 75%, with 165 of our total 220 staff having over 12 months' service. This is an increase in stability up from 67.9% from our previous report.

5.2 Turnover for permanent employees shows a 1% increase to 21%. As anticipated, exit interviews are indicating that salary and career progression are the main drivers.

6. **Finance**

6.1 The operating result to the end of July is a deficit of £43K, which is a favourable variance of £134K against forecast.

6.2 This variance arises as a result of income including interest being £143K higher than forecast and expenditure being £8K higher than forecast.

7. **Equality and diversity implications**

7.1 The purpose of this report is to report on operational and financial performance. There are no direct equality and diversity implications.

8. **Communications**

8.1 The development and publication of this report is reflective of our commitment to openness and transparency concerning our performance. We have undertaken, and will continue to develop, specific communications on each of the areas of reported performance. This includes information on our

Page 2 of 3
website, wider communications through the media and direct through our own publications and communications materials. These activities are designed to reach all our key interest groups including patients and their representatives, pharmacy professionals and their employees, education providers and others.

9. **Resource implications**

9.1 Resource implications are addressed within the report.

10. **Risk implications**

10.1 Failure to maintain an accurate register, and/or carry out our other regulatory functions efficiently and effectively could have implications on patient safety, and have a significant impact on the reputation of the GPhC.

10.2 Failure to accurately forecast / budget for revenues and expenditure could lead to inappropriate or inconsistent fee policies which could have an adverse impact on the GPhC’s reputation.

11. **Monitoring and review**

11.1 Council will receive a performance monitoring report at each meeting providing an update of the delivery of the GPhC’s regulatory functions and finances.

**Recommendations**

The Council is asked to note and comment on the performance information presented at Appendix 1

*Duncan Rudkin, Chief Executive & Registrar*

*General Pharmaceutical Council*

duncan.rudkin@pharmacyregulation.org

*Tel 020 3713 7811*

28 August 2015
Performance Monitoring Report

end July 2015
1. **Customer Services**

1.1 **Registrations by Month**

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>51</td>
<td>1752</td>
<td>559</td>
<td>123</td>
<td>376</td>
<td>211</td>
<td>206</td>
<td>67</td>
<td>62</td>
<td>81</td>
<td>58</td>
<td>59</td>
<td>66</td>
</tr>
<tr>
<td>Pharmacy Technicians</td>
<td>89</td>
<td>134</td>
<td>196</td>
<td>154</td>
<td>136</td>
<td>127</td>
<td>108</td>
<td>162</td>
<td>77</td>
<td>75</td>
<td>88</td>
<td>65</td>
<td>92</td>
</tr>
<tr>
<td>Registered Pharmacies</td>
<td>29</td>
<td>28</td>
<td>28</td>
<td>32</td>
<td>23</td>
<td>14</td>
<td>37</td>
<td>36</td>
<td>47</td>
<td>18</td>
<td>35</td>
<td>43</td>
<td>31</td>
</tr>
</tbody>
</table>

1.2 **Registration Totals**

<table>
<thead>
<tr>
<th>Register</th>
<th>Total at Jul 15</th>
<th>Budgeted Total</th>
<th>Variance</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pharmacists</td>
<td>50,189</td>
<td>50,393</td>
<td>-204</td>
</tr>
<tr>
<td>Pharmacy Technicians</td>
<td>22,805</td>
<td>22,092</td>
<td>715</td>
</tr>
<tr>
<td>Registered Pharmacies</td>
<td>14,373</td>
<td>14,445</td>
<td>-71</td>
</tr>
</tbody>
</table>

**Commentary 1:**
Register volumes continue to be stable on a month-to-month basis.
1.3  Median application processing times for pharmacists - 28 days or less

<table>
<thead>
<tr>
<th>Median application processing times for pharmacists (days) 01/07/2014 - 31/07/2015</th>
<th>Median application processing times for pharmacy technicians (days) 01/07/2014 - 31/07/2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application receipt to approval</td>
<td>Application receipt to approval</td>
</tr>
<tr>
<td>15</td>
<td>1</td>
</tr>
<tr>
<td>Application receipt to entry</td>
<td>Application receipt to entry</td>
</tr>
<tr>
<td>21</td>
<td>5</td>
</tr>
</tbody>
</table>

Commentary 2: The median approval times for approvals for pharmacists and pharmacy technicians have remained consistent with the previous period. The median application receipt to entry time for pharmacists (21 days) remains unchanged, whilst we have seen a minor increase to entry time for pharmacy technicians by one day.

This minor increase can be partially explained by the necessary shift in the focus of the application processing teams having had to process and take payments for over 2900 registration assessment applications, circa 3000 pre-registration applications and ensuring that payments for over 900 new pharmacist applicants who were eligible to enter the register on the 1 August were taken in good time to ensure registration by the due date.

1.4  Contact Centre

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Calls made to GPhC</td>
<td></td>
<td>6506</td>
<td>5792</td>
<td>6626</td>
<td>7699</td>
<td>4586</td>
<td>3466</td>
<td>3927</td>
<td>3786</td>
<td>4329</td>
<td>4190</td>
<td>6200</td>
<td>5255</td>
<td>7566</td>
</tr>
<tr>
<td>Calls answered within 20</td>
<td>&gt;80%</td>
<td>50.1%</td>
<td>83.7%</td>
<td>81.9%</td>
<td>77.8%</td>
<td>84.8%</td>
<td>77.9%</td>
<td>82.7%</td>
<td>89.8%</td>
<td>90.0%</td>
<td>90.8%</td>
<td>85.0%</td>
<td>90.2%</td>
<td>77.8%</td>
</tr>
<tr>
<td>seconds (%)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Calls abandoned (%)</td>
<td>&lt;5%</td>
<td>2.9%</td>
<td>2.3%</td>
<td>2.7%</td>
<td>5.3%</td>
<td>2.7%</td>
<td>5.5%</td>
<td>3.8%</td>
<td>1.6%</td>
<td>1.6%</td>
<td>1.2%</td>
<td>1.5%</td>
<td>1.0%</td>
<td>2.5%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Correspondence</th>
<th>Email actioned within 2 days (%)</th>
<th>KPI</th>
<th>Jul 14</th>
<th>Aug 14</th>
<th>Sep 14</th>
<th>Oct 14</th>
<th>Nov 14</th>
<th>Dec 14</th>
<th>Jan 15</th>
<th>Feb 15</th>
<th>Mar 15</th>
<th>Apr 15</th>
<th>May 15</th>
<th>Jun 15</th>
<th>Jul 15</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>&gt;90%</td>
<td>91.4%</td>
<td>98.5%</td>
<td>100%</td>
<td>98.0%</td>
<td>98.0%</td>
<td>100%</td>
<td>99.1%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td></td>
</tr>
</tbody>
</table>

**Commentary 3:**

This period is a busy time of year for the contact centre. There are three main factors driving volumes: the start of the new pre-registration year for new students, the registration assessment sitting and the release of the results in late July, and the high number of successful pre-registration candidates applying to join the register. This culminates in late July, when the registration assessment results are released. There are only a few days before all successful candidates wish to join the register on 1 August. In addition, many unsuccessful candidates contact us for help & advice about sitting again in September. This spikes significant call volumes over a short period, meaning that although calls are able to be answered (with abandonment rates well within the 5% KPI); the percentage of calls able to be answered within 20 seconds is reduced for that short period.
1.1 Continuing Professional Development (CPD)

### CPD Volumes

<table>
<thead>
<tr>
<th>CPD Volumes</th>
<th>Batch 4</th>
<th>Batch 5</th>
<th>Batch 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Records Requested</td>
<td>1965</td>
<td>1962</td>
<td>1963</td>
</tr>
<tr>
<td>Records Submitted by Deadline</td>
<td>1826</td>
<td>1832</td>
<td>1802</td>
</tr>
<tr>
<td>Timely Compliance</td>
<td>92.9%</td>
<td>93.4%</td>
<td>91.8%</td>
</tr>
</tbody>
</table>

### Submission Issues

<table>
<thead>
<tr>
<th></th>
<th>Batch 4</th>
<th>Batch 5</th>
<th>Batch 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extensions</td>
<td>Extension Requests</td>
<td>57</td>
<td>51</td>
</tr>
<tr>
<td></td>
<td>Ext Requests Granted</td>
<td>47</td>
<td>47</td>
</tr>
<tr>
<td>Incomplete</td>
<td>Incomplete Records</td>
<td>156</td>
<td>136</td>
</tr>
<tr>
<td>Problem Submissions</td>
<td>Problem Submissions</td>
<td>1</td>
<td>4</td>
</tr>
</tbody>
</table>

### Non-compliance Action

<table>
<thead>
<tr>
<th></th>
<th>1st Reminder</th>
<th>2nd Reminder</th>
<th>NIR (Notice of Intention to Remove)</th>
<th>NOR (Notice Of Removal)</th>
<th>Removals</th>
<th>Rem. Measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reminders</td>
<td>92</td>
<td>83</td>
<td>38</td>
<td>19</td>
<td>15</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>55</td>
<td>46</td>
<td>25</td>
<td>16</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>38</td>
<td>25</td>
<td>34</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>19</td>
<td>16</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
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<tr>
<td></td>
<td>-</td>
<td>-</td>
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<td></td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

*Data not yet available: A full request and review cycle i.e. initial request to removal for non-compliance, if appropriate, concludes within 5 months.*

Commentary 4:
Initial timely compliance across batches 4-6 ranged between 92% and 94%, consistent with the previous batches 1, 2 and 3.
2. Fitness to Practise (FtP)


<table>
<thead>
<tr>
<th>2.11 All cases triaged during this period</th>
<th>453</th>
</tr>
</thead>
<tbody>
<tr>
<td>Of which cases triaged within 3 days</td>
<td>435 (96%)</td>
</tr>
</tbody>
</table>

Table: Of all cases opened at any time

<table>
<thead>
<tr>
<th></th>
<th>No. of cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>All stream 1 cases closed pre-IC</td>
<td>167</td>
</tr>
<tr>
<td>Of which closed within 3 months</td>
<td>130 (78%)</td>
</tr>
<tr>
<td>All stream 2 cases closed pre-IC</td>
<td>108</td>
</tr>
<tr>
<td>Of which closed within 10 months</td>
<td>90 (83%)</td>
</tr>
<tr>
<td>All cases closed or referred at investigating committee (IC)</td>
<td>36</td>
</tr>
<tr>
<td>Of which reached IC within 12 months</td>
<td>25 (69%)</td>
</tr>
<tr>
<td>All fitness to practise committee cases closed</td>
<td>28</td>
</tr>
<tr>
<td>Of which closed within 24 months</td>
<td>21 (78%)</td>
</tr>
</tbody>
</table>

Commentary 5:
Performance has been positive over this reporting period. There have been improvements in four out of the five performance standards. Of note is the performance improvement in the percentage of cases closed at FtPC within 24 months; this rose to 78% (21 cases), up from 42% (five cases) in the last report. This represents a significant improvement, although performance will fluctuate from month to month depending upon how many of the older cases being moved through are listed. Performance has reduced in the proportion of stream 1 cases closed within three months, largely due to the continuing increases in concerns received; although the volume of stream 1 cases closed has increased from an average of 46 closures per month in the last report, to an average of 57 closures per month in this reporting period.
2.2 Case received and closed

 Commentary 6:

 In both May and June, more cases were closed than received. In July, the highest number of concerns received in a month was recorded, at 182. As a result, the overall open caseload has risen by just 14 to 711 since the last reporting period.
## 2.3 Case load age profile

<table>
<thead>
<tr>
<th>Age Profile</th>
<th>2014 No. of cases</th>
<th>2014 %</th>
<th>2015 No. of cases</th>
<th>2015 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 6 Months Old</td>
<td>No. cases</td>
<td></td>
<td>No. cases</td>
<td></td>
</tr>
<tr>
<td></td>
<td>July</td>
<td>September</td>
<td>November</td>
<td>January</td>
</tr>
<tr>
<td>Under 6 Months Old</td>
<td>317</td>
<td>312</td>
<td>320</td>
<td>341</td>
</tr>
<tr>
<td></td>
<td>47%</td>
<td>48%</td>
<td>50%</td>
<td>51%</td>
</tr>
<tr>
<td>6-12 Months Old</td>
<td>No. cases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>July</td>
<td>September</td>
<td>November</td>
<td>January</td>
</tr>
<tr>
<td>6-12 Months Old</td>
<td>193</td>
<td>163</td>
<td>146</td>
<td>159</td>
</tr>
<tr>
<td></td>
<td>29%</td>
<td>25%</td>
<td>23%</td>
<td>24%</td>
</tr>
<tr>
<td>12-15 Months Old</td>
<td>No. cases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>July</td>
<td>September</td>
<td>November</td>
<td>January</td>
</tr>
<tr>
<td>12-15 Months Old</td>
<td>32</td>
<td>42</td>
<td>44</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>5%</td>
<td>6%</td>
<td>7%</td>
<td>3%</td>
</tr>
<tr>
<td>15 Months Old and Over</td>
<td>No. cases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>July</td>
<td>September</td>
<td>November</td>
<td>January</td>
</tr>
<tr>
<td>15 Months Old and Over</td>
<td>131</td>
<td>134</td>
<td>132</td>
<td>146</td>
</tr>
<tr>
<td></td>
<td>19%</td>
<td>21%</td>
<td>21%</td>
<td>22%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>No. cases</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>July</td>
<td>September</td>
<td>November</td>
<td>January</td>
</tr>
<tr>
<td>Grand Total</td>
<td>673</td>
<td>651</td>
<td>642</td>
<td>666</td>
</tr>
<tr>
<td></td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
<td>100%</td>
</tr>
</tbody>
</table>
Commentary 7:

Direction of travel in reducing the age profile of the open caseload continues to be positive. The open caseload is getting younger. The number of open cases over 12 months old has reduced to 151, from 162 cases in the last report. As a result, 21% of our open caseload is now older than 12 months, continuing the positive trend. Within this cohort of cases, those cases over 15 months old have also reduced this reporting period, in line with one aspect of our plan to progress the older cases through the process. The number of cases over the age of 15 months old reduced by 12 to 129. Whilst the numbers of cases under the age of 6 months old is increasing, mirroring the increase in concerns received. Importantly, the numbers of open cases aged six-12 months old are continuing to reduce, demonstrating that we are managing to keep on top of the influx of cases at present, in line with the plan to progress newer cases through the process more efficiently.

In relation to the 151 open cases over the age of 12 months, 94 are now beyond the investigatory stage

- eight of these are before the IC awaiting a decision and are listed for IC meetings in August and September 2015;
- 12 are subject to an Interim Order
- 35 are in the listing process for scheduling to be heard at FtPC between October and December 2015
- 39 of these cases have been listed for hearing, and will be closed between August and December 2015.

The remaining 57 cases over the age of 12 months old are at the investigation stage. 16 of these are subject to third party investigation and therefore we are unable to progress those investigations. Of the 41 remaining live cases, they have scheduled investigation completion dates from August to December 2015.
## 2.4 Cases over 15 months

<table>
<thead>
<tr>
<th>Age profile of cases &gt; 15 months</th>
<th>End July 14</th>
<th>End January 14</th>
<th>End April 15</th>
<th>End July 15</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number of cases</td>
<td>%</td>
<td>Number of cases</td>
<td>%</td>
</tr>
<tr>
<td>15-19 months</td>
<td>58</td>
<td>44.3%</td>
<td>71</td>
<td>48.6%</td>
</tr>
<tr>
<td>20-24 months</td>
<td>29</td>
<td>22.1%</td>
<td>32</td>
<td>21.9%</td>
</tr>
<tr>
<td>25-29 months</td>
<td>22</td>
<td>16.8%</td>
<td>15</td>
<td>10.3%</td>
</tr>
<tr>
<td>30-34 months</td>
<td>11</td>
<td>8.4%</td>
<td>19</td>
<td>13.0%</td>
</tr>
<tr>
<td>35-39 months</td>
<td>3</td>
<td>2.3%</td>
<td>4</td>
<td>2.7%</td>
</tr>
<tr>
<td>40-42 months</td>
<td>4</td>
<td>3.1%</td>
<td>2</td>
<td>1.4%</td>
</tr>
<tr>
<td>43-50 months</td>
<td>3</td>
<td>2.3%</td>
<td>2</td>
<td>1.4%</td>
</tr>
<tr>
<td>&gt;50 Months</td>
<td>1</td>
<td>0.8%</td>
<td>1</td>
<td>0.7%</td>
</tr>
</tbody>
</table>
Commentary 8: Direction of travel in progressing the oldest cases through to closure remains positive and on track. A healthy 42 cases over the age of 15 months have been closed this reporting period. Cases older than 15 months old now represent 18% (129 cases) of the total open caseload at the end of July. This represents a reduction from 20% (141 cases) in the last report. 67% of the remaining cases in this age bracket (86 out of the 129) are past the investigation stage on their way to closure. Seven of these are currently before the IC; nine are subject to an Interim Order; 34 are awaiting listing before FtPC and 36 of these cases are currently listed for hearing between August and December 2015. Of the remaining 43 cases within this age profile (11%), 14 are subject to third party investigation and are on hold. 29 cases are still at the investigation stage with these investigations forecast to be completed between August and November 2015. Of the five cases over 40 months old, one case remains subject to a third party investigation, one case is scheduled with the IC, and the remaining three cases are listed before the FtPC in October and November 2015.
## 2.5 Concerns by type

**Concerns Received Aug 2014 – July 2015**

<table>
<thead>
<tr>
<th>Investigation Category</th>
<th>Number of cases</th>
<th>% of total cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Misconduct</td>
<td>1,053</td>
<td>62.4%</td>
</tr>
<tr>
<td>Misconduct (Professional Performance)</td>
<td>47</td>
<td>3.3%</td>
</tr>
<tr>
<td>Misconduct (Caution/Conviction)</td>
<td>10</td>
<td>0.7%</td>
</tr>
<tr>
<td>Caution/Conviction</td>
<td>61</td>
<td>3.7%</td>
</tr>
<tr>
<td>Health</td>
<td>20</td>
<td>1.2%</td>
</tr>
<tr>
<td>Other</td>
<td>40</td>
<td>2.3%</td>
</tr>
<tr>
<td>Hybrid</td>
<td>9</td>
<td>0.6%</td>
</tr>
<tr>
<td>Misconduct (Health)</td>
<td>9</td>
<td>0.6%</td>
</tr>
<tr>
<td>Professional Performance</td>
<td>5</td>
<td>0.3%</td>
</tr>
<tr>
<td>Restoration</td>
<td>10</td>
<td>0.6%</td>
</tr>
<tr>
<td>Out of Jurisdiction</td>
<td>400</td>
<td>24.6%</td>
</tr>
</tbody>
</table>

**Commentary 9:** The types and relative proportion of cases we have received over the last 11 months has not changed significantly since the last report.
2.6 Cases closed by stage

Commentary 10: In relation to case closures this reporting period, there has been a significant improvement in the number of cases closed at the FtP Committee and Stream 1 stages. 33 cases were closed at FtPC, compared to 19 in the last reporting period, and 167 cases were closed at Stream 1, in comparison to 135 previously. Notably, the highest number of Stream 1 cases was closed in July, 61.
2.7 DBS referrals

Commentary 11:
We have referred information in relation to seven cases to the DBS in this reporting period. There have been no referrals to Disclosure Scotland.

2.8 Appeals

Commentary 12:
There have been no new appeals this reporting period. We continue to have four live appeal cases, of which we expect two to conclude by the end of August. We await Court listing dates for the remaining two appeals.
2.9 Interim Orders

Commentary 13:
Performance in securing interim orders over this reporting period remains stable at three weeks. These are sought in circumstances where an order is necessary to protect the public, is in the public interest or is necessary to protect the registrant. This period includes the time from when we receive information which indicates the need for an interim order through until an interim order decision is made by FtPC. Since July 2014 the GPhC made 39 Interim Order Applications, of which 36 were granted and three were declined. Seven conditional practice orders and 29 suspension orders were made.
3. Inspection

3.1 Inspections Undertaken May, June, July 2015

<table>
<thead>
<tr>
<th></th>
<th>Routine Inspections</th>
<th>Follow Up Inspections</th>
<th>Pre-registration visits (pharmacy premises)</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 15 – Jul 15</td>
<td>805</td>
<td>69</td>
<td>91</td>
</tr>
</tbody>
</table>

3.2 Pharmacy premises not inspected

<table>
<thead>
<tr>
<th>Months since previous inspection</th>
<th>Feb 15</th>
<th>%</th>
<th>Apr 15</th>
<th>%</th>
<th>Jul 15</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Between 36 and 39 months</td>
<td>953</td>
<td>40%</td>
<td>988</td>
<td>35%</td>
<td>1,132</td>
<td>34%</td>
</tr>
<tr>
<td>Between 39 and 42 months</td>
<td>789</td>
<td>33%</td>
<td>893</td>
<td>31%</td>
<td>920</td>
<td>28%</td>
</tr>
<tr>
<td>Between 42 and 48 months</td>
<td>582</td>
<td>24%</td>
<td>794</td>
<td>28%</td>
<td>1,007</td>
<td>30%</td>
</tr>
<tr>
<td>Over 48 months</td>
<td>87</td>
<td>3%</td>
<td>177</td>
<td>6%</td>
<td>245</td>
<td>7%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>2,411</td>
<td>100%</td>
<td>2,852</td>
<td>100%</td>
<td>3,304</td>
<td>100%</td>
</tr>
</tbody>
</table>

Commentary 14:
Productivity is improving. The number of routine inspections undertaken in July was the second highest we have recorded since the new approach to inspection began. Almost half of the inspectors are now averaging 10 or more routine inspections each month, whilst continuing to manage other inspection and investigation activities, such as stream 1 cases. We continue to focus on addressing inconsistencies in productivity where they exist.

Commentary 15:
Whilst the number of pharmacies over the age of 48 months not inspected has increased, the rate of growth has slowed slightly. This follows the increased focus of inspectors in this category. From our monitoring to date, there is no evidence that those pharmacies that have waited the longest to be inspected demonstrate poorer performance. In addition, every pharmacy is visited if a concern is raised with us. Going forward, inspectors will now focus solely on the oldest pharmacies in their geographical areas to tackle the flow of pharmacies heading up to the 48 month figure. Additional capacity in the form of the new ‘floating inspector’ approach, focusing solely on inspections is helping, with positive early indications. Productivity is higher and provides a more flexible resource to target priority areas. Two more additional ‘floating’ inspectors will join us shortly in areas where we have the most pharmacies awaiting inspections.
3.3 Top 5 Standards Ranked as Not Met

<table>
<thead>
<tr>
<th>Standard Number</th>
<th>Standard Description</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The risks associated with providing pharmacy services are identified and managed</td>
<td>1</td>
</tr>
<tr>
<td>1.2</td>
<td>The safety and quality of pharmacy services are regularly reviewed and monitored</td>
<td>2</td>
</tr>
<tr>
<td>1.6</td>
<td>All necessary records for the safe provision of pharmacy services are kept and maintained</td>
<td>3</td>
</tr>
<tr>
<td>3.1</td>
<td>Premises are safe, clean, properly maintained and suitable for the pharmacy services provided</td>
<td>4</td>
</tr>
<tr>
<td>4.3</td>
<td>Medicines and medical devices are: obtained from a reputable source; safe and fit for purpose; stored securely; safeguarded from unauthorized access; supplied to the patient safely; and disposed of safely and securely</td>
<td>5</td>
</tr>
</tbody>
</table>

3.4 Top 5 Standards Ranked As Good

<table>
<thead>
<tr>
<th>Standard Number</th>
<th>Standard Description</th>
<th>Rank</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The risks associated with providing pharmacy services are identified and managed</td>
<td>1</td>
</tr>
<tr>
<td>1.2</td>
<td>The safety and quality of pharmacy services are regularly reviewed and monitored</td>
<td>2</td>
</tr>
<tr>
<td>2.4</td>
<td>There is a culture of openness, honesty and learning</td>
<td>3</td>
</tr>
<tr>
<td>4.2</td>
<td>Pharmacy services are managed and delivered safely and effectively</td>
<td>4</td>
</tr>
<tr>
<td>2.2</td>
<td>Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training</td>
<td>5</td>
</tr>
</tbody>
</table>

Commentary 16:
The standards most commonly rated ‘good’ remain the same. The standards most commonly rated ‘not met’ are also the same although there has been a small shift in the rankings of these.

We have undertaken a further quality assurance exercise to continue our development of the inspection reports. These are now incorporating much more clearly the ‘areas for improvement’ where a pharmacy is rated as ‘satisfactory’ and we have received some positive feedback on this through our strategic relationship management. We are also doing work to increase the consistency in how we write the summary judgements in reports, aiming to bring out the areas of good practice more clearly.
Commentary 17:

We have made improvements to the categorisation of complaints and negative feedback. Since April 2015 we have categorised complaints and negative feedback according to the new categories shown here.

To enable comparison with complaints received before April 2015, we have regrouped the old categories into the new categories according to an estimate of best-fit.
5. **Human Resources**

5.1 **Staff Turnover**

<table>
<thead>
<tr>
<th>Directorate</th>
<th>Permanent</th>
<th>Fixed-Term</th>
<th>Grand Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Executive Office</td>
<td>15</td>
<td>7</td>
<td>22</td>
</tr>
<tr>
<td>Inspection and Fitness to Practise</td>
<td>79</td>
<td>8</td>
<td>87</td>
</tr>
<tr>
<td>Policy &amp; Communications</td>
<td>32</td>
<td>6</td>
<td>40</td>
</tr>
<tr>
<td>Resources &amp; Customer Services</td>
<td>66</td>
<td>5</td>
<td>71</td>
</tr>
<tr>
<td><strong>Grand Total</strong></td>
<td>194</td>
<td>26</td>
<td>220</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Total permanent staff</th>
<th>Resignations</th>
<th>Turnover</th>
</tr>
</thead>
<tbody>
<tr>
<td>194</td>
<td>41</td>
<td>21%</td>
</tr>
</tbody>
</table>

**Stability Rate** 77.8%

**Commentary 18:**

The overall stability rate is 75%, with 165 of our total 220 staff having over 12 months’ service. This is an increase in stability up from 67.9% from our previous report. For permanent employees, this figure rises to 77.8%. Turnover for permanent employees shows a 1% increase to 21%. As anticipated, exit interviews are indicating that salary and career progression are the main drivers. The economic upturn is now having a marked effect on both turnover and recruitment. The greatest turnover is within the lower and middle management grades. 30% of vacant posts since 1 May 2015 have been filled by internal candidates.
Leavers From August 1st, 2014 - July 31st, 2015

- Executive Office: 5
- Inspection and Fitness to Practise: 16
- Policy & Communications: 6
- Resources & Customer Services: 20

Starters From August 1st, 2014 - July 31st, 2015

- Executive Office: 6
- Inspection and Fitness to Practise: 22
- Policy & Communications: 7
- Resources & Customer Services: 19
5.2 Staff Sickness

Commentary 19: In conjunction with line managers, we continue to monitor absence rates and to address any specific concerns when they arise. The figures shown above exclude long term sickness absence. We currently have two individuals within this category.
6. Financial Performance

6.1 GPhC Balance Sheet as at 31 July 2015

**Commentary 19:** The balance sheet shows total fixed assets of £6.5m which is made up of works carried out to our offices, new office furniture, computer equipment and development of the CRM project. There may be a write off to the income and expenditure statement in future months relating to the HR access system project.

Current liabilities of £12.4m are primarily made up of deferred income £10.7m which relates to monies received in relation to fee income and the working capital grants provided by the DH, a PAYE tax liability of £0.2m and accruals £1.2m.

Capital Contributions of £3.9m represent the amount that the landlord has contributed to date towards the fit-out costs for our offices. The landlord is meeting 85% of these costs. They will be credited over 10 years to the Income & Expenditure Account, thus reducing the cost of renting our offices by c. £450k per year.
## 6.2 Management Accounts July 2015

<table>
<thead>
<tr>
<th></th>
<th>July 2015</th>
<th>Actual</th>
<th>F/cast</th>
<th>Variance</th>
<th>Budget to 31/03/16</th>
<th>Actual</th>
<th>Budget</th>
<th>Variance</th>
<th>Budget to 31/03/16</th>
<th>Actual</th>
<th>Forecast</th>
<th>Variance</th>
<th>Budget to 31/03/16</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Income</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacist Income</td>
<td>1,154</td>
<td>1,044</td>
<td>110</td>
<td></td>
<td></td>
<td>4,226</td>
<td>4,147</td>
<td>79</td>
<td></td>
<td>4,226</td>
<td>4,116</td>
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<td>1,188</td>
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<td></td>
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<td>862</td>
<td>845</td>
<td>17</td>
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<td>862</td>
<td>856</td>
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<td>Pre-Registration Income</td>
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<td>DH Grant Income</td>
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<td><strong>Total Income</strong></td>
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<td>1,687</td>
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<td>7,368</td>
<td>6,989</td>
<td>379</td>
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<td>7,368</td>
<td>7,229</td>
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<td><strong>Expenditure</strong></td>
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<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>Chief Executive</td>
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<td>(466)</td>
<td>121</td>
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<td>(351)</td>
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<td>(1,406)</td>
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<td>(1,099)</td>
<td>(47)</td>
<td></td>
<td>(1,156)</td>
<td>(1,158)</td>
<td>12</td>
<td>(3,328)</td>
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<td>(2,240)</td>
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<td>Council &amp; Governance</td>
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<td>Contribution from Landlord</td>
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<td>147</td>
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<td>(185)</td>
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<td>4</td>
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<td><strong>Total Occupancy Costs</strong></td>
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<td>(664)</td>
<td>(660)</td>
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<td>(1,988)</td>
</tr>
<tr>
<td>Total Contingency Costs</td>
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<td>(7)</td>
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<td></td>
<td></td>
<td>(7,470)</td>
<td>(7,649)</td>
<td>179</td>
<td></td>
<td>(7,470)</td>
<td>(7,461)</td>
<td>(8)</td>
<td>(23,102)</td>
</tr>
<tr>
<td>Net Operating Surplus/(Deficit) before interest &amp; tax</td>
<td>(46)</td>
<td>(177)</td>
<td>131</td>
<td></td>
<td></td>
<td>(102)</td>
<td>(659)</td>
<td>557</td>
<td></td>
<td>(102)</td>
<td>(232)</td>
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<td>(2,020)</td>
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<td>Interest Receivable</td>
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<td>74</td>
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<td>18</td>
<td></td>
<td>74</td>
<td>69</td>
<td>5</td>
<td>168</td>
</tr>
<tr>
<td>Net Operating Surplus/(Deficit) before tax</td>
<td>(27)</td>
<td>(158)</td>
<td>131</td>
<td></td>
<td></td>
<td>(27)</td>
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<td>(27)</td>
<td></td>
<td>(27)</td>
<td>(163)</td>
<td>136</td>
<td>(1,852)</td>
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<td>Corporation Tax Payable</td>
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<td>(10)</td>
<td>(5)</td>
<td></td>
<td>(10)</td>
<td>(14)</td>
<td>(1)</td>
<td>(31)</td>
</tr>
<tr>
<td>Net Operating Surplus/(Deficit) after tax</td>
<td>(31)</td>
<td>(162)</td>
<td>131</td>
<td></td>
<td></td>
<td>(43)</td>
<td>(11)</td>
<td>(32)</td>
<td></td>
<td>(43)</td>
<td>(177)</td>
<td>134</td>
<td>(1,883)</td>
</tr>
</tbody>
</table>
Commentary 20:

Operating surplus/(deficit) after interest and tax

The operating result to the end of July is a deficit of £43K, which is a favourable variance of £134K against forecast.

This variance arises as a result of income including interest being £143K higher than forecast and expenditure being £8K higher than forecast.

Income

- **Pharmacist Income** is £110K higher than forecast; this is primarily due to a timing difference relating to application fees. On average, we have received 880 additional application fees this month, these fees were forecast for August.

- **Premises Income** is £9K higher than forecast; this is mainly due to an increase in applications in the month – an average of 9 additional application fees.

- **Technician Income** is £6K higher than forecast; this is due to an average increase of 36 applications fees this month.

- **Cost Recovery Income** is £12K higher than forecast; this is for the recovery of high court legal costs.

Expenditure

- **Professional costs** are £32K higher than forecast year to date; this relates to a number of factors – there was a £9K overspend in associates for a review carried out, there has also been a £23K overspend in CPD reviews which was not forecast in July.

- **Marketing Costs** are £9K higher than forecast year to date – this is due to costs for designing the IC guidance consultation documentation which was not in the forecast.

- **IT Costs** are £16K lower than forecast year to date – this is a due to a delay in IT project costs which have not started yet.

- The **contingency** has not been fully utilised realising savings of £15K year to date within ‘Other costs’.
6.3 Expenditure by Cost Category

Expenditure Analysis by Cost Category

6.4 Headcount Report – Actual/Budget Forecast

Total expenditure incurred per cost category expressed as a percentage

Note: This is based on FTE staff, including fixed term contractors, on the payroll at the payroll cut-off date.
7. **Accreditation Data**

7.1 **Accreditation/recognition activity September 2014 – July 2015**

<table>
<thead>
<tr>
<th>Course</th>
<th>Event type</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>MPharm degree</td>
<td>accreditation</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td>reaccreditation</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>interim visit</td>
<td>7</td>
</tr>
<tr>
<td>Independent prescribing:</td>
<td>accreditation</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td>reaccreditation</td>
<td>15</td>
</tr>
<tr>
<td></td>
<td>monitoring visit</td>
<td>3</td>
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<tr>
<td>Level 2 Medicines Counter Assistant/Dispensing Assistant:</td>
<td>accreditation</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>reaccreditation</td>
<td>0</td>
</tr>
<tr>
<td>Overseas Pharmacists’ Assessment Programme (OSPAP)</td>
<td>reaccreditation</td>
<td>4</td>
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**Commentary 21:**

This year was a particularly heavy one, with 45 events - this stretched the resources of the education function to the limit. Fortunately, while next year is busy, the number of events will be a more manageable 31.

For some time the GPhC has been in discussion with the University of Central Lancashire (UCLan) about MPharm recruitment concerns and other matters. As a result of the discussion, UCLan agreed to implement a voluntary action plan, including a significant restriction on the number of students entering the MPharm degree in 2015. UCLan has provided us with updates on recruitment throughout clearing.
Public business

Unconfirmed minutes of the Audit and Risk Committee,
23 July 2015

Recommendations
The Council is asked to note the unconfirmed minutes of the Audit and Risk Committee.
Minutes of the Audit and Risk Committee meeting held on Thursday, 23 July 2015 at 25 Canada Square, London, at 2:45pm

Minutes of the public session

Present
   David Prince – Chair
   Judy Worthington
   Soraya Dhillon
   Mohammed Hussain
   Hilary Daniels

Apologies
   Bernard Kelly (Director of Resources and Customer Services) (non-member)
   Jenny Brown (Grant Thornton) (non-member)

In attendance
   Duncan Rudkin (Chief Executive and Registrar)
   Hugh Simpson (Director of Policy and Communications)
   Matthew Hayday (Head of Governance)
   Paula Woodward (Council Secretary)
   Catherine Neil (Administrator)
   Heather Walker (Head of Corporate Business Support and Development)
   Carole Gorman (Governance and Assurance Officer)
   Sharon Charles (Professionals Regulation Manager)
   Sarah Hilary (Moore Stephens)
   Bill Mitchell (Moore Stephens)

Public business

1. WELCOME AND INTRODUCTORY REMARKS

1.1. The chair welcomed everyone to the meeting and thanked John Allsop for the informative workshop session on risk management software and revised risk appetite statement that had been held immediately prior to the meeting.

1.2. Matthew Hayday informed the committee that Paula Woodward, Council Secretary, had resigned from the GPhC to take on an opportunity within NHS England. The committee congratulated PW and thanked her for all the support she had provided the committee.

1.3. The committee welcomed Catherine Neil, Administrator, to the meeting. Part of Catherine’s role would be to support the secretariat for Council and its committees.
2. **MINUTES OF PREVIOUS MEETING**
   
2.1. The minutes of the meeting held on 28 May 2015, public and confidential sessions, were agreed as a true record subject to the addition of noting the committee’s thanks to Saleem Akuji, financial accountant, for his work on the end of year accounts, particularly in the absence of the Director of Resources and Customer Services and with the substantive Head of Finance only recently in post.

3. **DECLARATIONS OF INTEREST**
   
3.1. There were no declarations of interest.

4. **ACTIONS AND MATTERS ARISING**
   
4.1. In relation to the organisation’s reporting of equality, diversity and inclusion issues (minute 13.7) Matthew Hayday (MH) informed the committee that these would now be reported to Council via the corporate plan reporting process. He said that a paper setting out the new approach would be reviewed by the Executive Board at its next meeting.

   4.2. The committee noted that the actions from previous meetings had been completed and were marked as closed.

   4.3. There were no further actions or matters arising.

5. **ASSURANCE REVIEW: EFFICIENCY AND EFFECTIVENESS**
   
5.1. Heather Walker (HW) gave a presentation to the committee which outlined the development of the organisation’s efficiency and effectiveness review. She reported that the review would be carried out within current planning processes rather than as a standalone project.

5.2. HW informed the committee that the review would involve budget holders at all levels in order to inform both the forecasting for the remainder of the current year as well as helping with the preparation of next year’s budget.

5.3. Duncan Rudkin (DR) reported that one key element of the review would be the further development of a variety of metrics to ensure that the impact of any changes could be measured and monitored.

5.4. During the discussion, the committee noted that the review was as much about changing the culture to make better use of current resources to ensure best value for money rather than simply reducing budgets.

5.5. The committee made a number of comments and suggestions about the proposals, including that the work that had already taken place to improve efficiency in a number of areas should be recognised.

5.6. The committee noted the proposals.

6. **ASSURANCE REVIEW: MOUS AND INFORMATION SHARING**
   
6.1. Hugh Simpson (HS) gave a presentation to the committee which set out how the memoranda of understanding (MoUs) with various other organisations had been developed. Carole Gorman (GG) and Sharon Charles (SC) then
presented examples of how those MoUs had resulted in more efficient information sharing between the GPhC and those organisations.

6.2. In response to a member’s question, HS reported that although there had been some difficult issues, progress had been very good, particularly where the information required was about a particular case or individual. However, where the relationship with another organisation was more complex or involved large amounts of data, these MoUs were taking longer to develop.

6.3. During the discussion, the committee noted that the information requests that had been received and dealt with since the introduction of the various MoUs were ‘two way’ in that the GPhC provided information to other organisations as well as requesting it.

6.4. ACTION: a brief update to be presented to the committee in 2016 on progress

6.5. ACTION: the report on the development of the MoUs that would be submitted to the minister to be circulated to the committee.

6.6. The committee noted the development of the MoUs and the work carried out to date to develop others.

7. INTERNAL AUDIT: Q1 PERFORMANCE REPORT

7.1. John Allsop (JA) drew members’ attention to the key points in the report. Bill Mitchell (BM) summarised the findings of the internal audit on the CRM project.

7.2. The committee noted the Q1 progress report and the CRM internal audit report.

8. RISK MANAGEMENT UPDATE

8.1. John Allsop (JA) outlined the changes that had been made to the risk management policy and guidelines.

8.2. The committee suggested that the wording for the levels of risk appetite should be different to that for risks: “adverse, cautious, ambitious” was suggested as an alternative.

8.3. The committee noted the updated risk management policy and guidelines.

9. REVIEW OF COMMITTEE REMIT AND MEMBERSHIP

9.1. The committee noted the amendment of its terms of reference in line with the raising concerns (whistleblowing) policy and recommended the changes to Council.

10. ANY OTHER BUSINESS

10.1. There being no further business, the meeting closed at 4:05pm.

DATE OF NEXT MEETING

Wednesday 14 October 2015, 10.00am.
Public business

Policy and Procedure Review

Purpose
To seek Council’s approval for the policies within its remit that have been recently reviewed.

Recommendations
The Council is asked to approve the emergency registration policy.

1. Introduction
1.1 Authority in a number of policy areas is reserved to Council within the Scheme of Delegation. This paper presents the review of one of those policies and asks for Council’s approval.

2. Emergency registration policy
2.1 The policy on temporary registration arrangements in the event of an emergency involving loss of human life or human illness (emergency registration policy) is a requirement of the Pharmacy Order 2010.

2.2 There are no proposed amendments to this policy as it remains current. The next planned review will be November 2017.

3. Equality and diversity implications
3.1 Equality and diversity implications are considered in the development of individual policies.

4. Communications
4.1 The revised policy will be placed on the GPhC’s intranet and, as it is externally facing, on the website.

5. Resource implications
5.1 There are no resource implications arising from this paper.
6. **Risk implications**
6.1 Without clearly defined policies and procedures decisions taken by the GPhC may be subject to challenge.

7. **Monitoring and review**
7.1 Each policy has a review date at which point the effectiveness of the policy is reviewed as well as currency with relevant guidance and best practice. Policies are reviewed earlier if there are changes in legislation which need to be reflected.

**Recommendations**

The Council is asked to approve the emergency registration policy.

*Matthew Hayday, Head of Governance*  
*General Pharmaceutical Council*  
*matthew.hayday@pharmacyregulation.org*  
*Tel 020 3713 7809*  

27 August 2015
Policy on temporary registration arrangements in the event of an emergency involving loss of human life or human illness (emergency registration policy)

1. **Introduction**

1.1 We have powers to register temporarily fit, proper and suitably experienced people to act as pharmacists and pharmacy technicians if an emergency is declared by the Secretary of State. We also have powers to annotate the entries of registrants in Part 1 and Part 2 of the register during an emergency. These powers will cease when the emergency ends.

1.2 During an emergency the General Pharmaceutical Council’s operating capacity could be seriously compromised, so it is essential that preparations are made in advance to allow us to bring suitable additional people onto the Register rapidly and efficiently in an emergency.

2. **Purpose of policy**

2.1 Under article 34 of the Pharmacy Order 2010, the Registrar may temporarily enter in Part 1 (pharmacists) or Part 2 (pharmacy technicians) of the Register persons or specified groups of persons considered fit, proper and suitably experienced during an emergency.

2.2 Under article 35 of the Pharmacy Order 2010, the Registrar may temporarily annotate entries in Part 1 (pharmacists) or Part 2 (pharmacy technicians) of the Register persons or specified groups of persons considered fit, proper and suitably experienced during an emergency.

2.3 The purpose of this policy is to identify the persons or specified groups of persons considered fit, proper and suitably experienced to be temporarily registered or annotated during an emergency.

3. **Policy statement**

3.1 Under article 34 of the Pharmacy Order 2010, and upon the declaration of an emergency by the Secretary of State, the Registrar may register the following groups in Part 1 (pharmacists) for the duration of the emergency in descending order of priority

- Former registrants on Part 1 of the Register (pharmacists) who were voluntarily removed within the last two years and whose fitness to practise is not impaired
- Post-MPharm pre-registration trainee pharmacists with recent satisfactory progress reports and whose fitness to practise is not impaired
• Former registrants on Part 1 of the Register (pharmacists) who were removed for non renewal of registration within the last two years and whose fitness to practise is not impaired
• Registrants on Part 2 of the Register (pharmacy technicians)

3.2 Under article 34 of the Pharmacy Order 2010, and upon the declaration of an emergency by the Secretary of State, the Registrar may register the following groups in Part 2 (pharmacy technicians) for the duration of the emergency in descending order of priority
• Former registrants on Part 2 of the Register (pharmacy technicians) who were voluntarily removed within the last two years and whose fitness to practise is not impaired
• Post-MPharm pre-registration trainee pharmacists with recent satisfactory progress reports and whose fitness to practise is not impaired
• Former registrants on Part 2 of the Register (pharmacy technicians) who were removed for non renewal of registration within the last two years and whose fitness to practise is not impaired
• Pharmacy students who are undertaking year 3 or 4 of the MPharm

3.3 Under article 35 of the Pharmacy Order 2010, and upon the declaration of an emergency by the Secretary of State, the Registrar may annotate the following groups as prescribers for the duration of the emergency
• Registrants in Part 1 of the Register (pharmacists)

4. Application of policy
4.1 We will maintain up to date data on former registrants who fall under the categories listed above from which to prepare the temporary registers. This information will be updated on a rolling basis but will remain unpublished until such time as an emergency is declared.

4.2 The implementation of this policy will include an operations strategy to publish, maintain, review and close the temporary registers if an emergency is declared and a communication strategy to provide information to registrants, patients and the public and others about temporary registration before, during and after an emergency

5. Measurement and evaluation
5.1 After an emergency, we will hold a review on the implementation of this policy and seek feedback from staff, registrants, patients and the public and other stakeholders.

5.2 The policy will be evaluated on an annual basis to review if the persons and groups identified are still considered fit, proper and suitably experienced to be temporarily registered or annotated during an emergency.
5.3 The policy will be reviewed if there are any amendments or additions to the categories of annotation to Part 1 or Part 2 of the Register.

**Terry Orford, Head of Customer services, Resources and Customer Services**
Reference: XXXXXXXX
Effective date: XXXXXXXX
Review date: November 2017
Agreed by: XXXXXXXXXXXX