

Council meeting

8 February 2018

13:30 to 15:45 approx.

Council Room 1, 25 Canada Square, London E14 5LQ

Public business

| | |
|---|------------------------------|
| 1. Attendance and introductory remarks | Nigel Clarke |
| 2. Declarations of interest <i>Public items</i> | All |
| 3. Minutes of last meeting <i>Public session on 07 December 2017</i> | Nigel Clarke |
| 4. Workshop summary – 7 December 2017 | Nigel Clarke |
| 5. Actions and matters arising | Nigel Clarke |
| 6. Performance monitoring and annual plan progress report <i>For noting</i> | 18.02.C.01 Megan Forbes |
| 7. Consulting on education & training standards for pharmacist independent prescribers <i>For approval</i> | 18.02.C.02 Damian Day |
| 8. Promoting professionalism, reforming regulation (Department of Health consultation) <i>For noting</i> | 18.02.C.03 Priya Warner |
| 9. Engagement and communications report <i>For noting</i> | 18.02.C.04 Rachael Oliver |
| 10. Deputising arrangements for Chair of Council 2018/19 <i>For noting</i> | 18.02.C.05 Pascal Barras |
| 11. Audit and Risk Committee; unconfirmed minutes - 23 January 2018 <i>For noting</i> | 18.02.C.06 Digby Emson |
| 12. Any other public business | Nigel Clarke |

Confidential business

| | |
|--|--|
| 13. Declarations of interest <i>Confidential items</i> | All |
| 14. Minutes of last meeting <i>Confidential session on 7 December 2017</i> | Nigel Clarke |
| 15. Confidential actions and matters arising | Nigel Clarke |
| 16. Audit and Risk Committee; unconfirmed, confidential minutes - 23 January 2018 | 18.02.C.07 Digby Emson |
| 17. Reappointment of the Chair <i>For approval</i> | 18.02.C.08 Berwyn Owen and David Prince |
| 18. Any other confidential business | Nigel Clarke |

Date of next meeting

Thursday, 08 March 2018

Minutes of the Council meeting held on Thursday 7 December 2017 at 25
Canada Square, London at 13:45

TO BE CONFIRMED 8 FEBRUARY 2017

Minutes of the public session

Present

Nigel Clarke (Chair)

Mary Elford

Digby Emson

Mark Hammond

Mohammed Hussain

Joanne Kember

Alan Kershaw

Elizabeth Mailey

Evelyn McPhail

Arun Midha

Berwyn Owen

David Prince

Samantha Quaye

Jayne Salt

Apologies

None

In attendance

Duncan Rudkin (Chief Executive and Registrar)

Megan Forbes (Deputy Chief Executive and Director of Corporate Resources)

Claire Bryce-Smith (Director of Insight, Intelligence and Inspection)

Matthew Hayday (Director of Fitness to Practise)

Francesca Okosi (Director of People)

Mark Voce (Director of Education and Standards)

Laura McClintock (Chief of Staff)

Carole Gorman (Governance and Assurance Manager)

Helen Dalrymple (Council Secretary)

Elaine Mulingani (Associates and Partners Manager) – item 71

Elisabeth Davis (Chair of the Appointments Committee) – item 71

Priya Warner (Head of Policy and Standards) – item 72

Osama Ammar (Head of Revalidation) – item 72 and 73

Damian Day (Head of Education) – item 75

66. Attendance and introductory remarks

- 66.1. The Chair welcomed all present to the meeting. There were no apologies.

67. Declarations of interest

- 67.1. Council agreed that members would make any declarations of interest before each item.

68. Minutes of the last meeting

- 68.1. Following members' comments, the minutes had been amended as follows:
- 59.3. *[Members] regretted that data on ethnicity, which they had had previously, was not available.*
- 61.3. *Members highlighted that they were aware that recruitment for five members of Council would begin next year*
- 64.2. *'pharmacy technician' had been amended to 'registrant'*
- 68.2. Members sought clarity on whether they should be named in minutes when a vote was held. The Standing Orders for Council allowed either the numbers of who had voted or members' names to be used.
- 68.3. It was agreed that it should be made clear when the Chair had withdrawn from the process.
- 68.4. Using numbers was consistent with not attributing views to individuals; members were collectively responsible for decisions made as a Council. Members considered that an exception may be made if specifically requested. It would continue to be recorded when an individual had removed themselves from a discussion due to a conflict of interest.
- 68.5. Members agreed that numbers would be used in the minutes when recording a vote by Council. This would be kept under review. Should any member wish to record a strongly held opinion it would be done so at the Chair's discretion.
- 68.6. **The minutes of the public session held on the 9 November 2017 were confirmed as a fair and accurate record.**

69. Workshop summary – 9 November 2017

- 69.1. Following members' comments the penultimate sentence of para 2.2 now read *'The Council noted how the elements of quality were managed differently between pharmacist and pharmacy technician education and training.'*
- 69.2. Members said that they would like the summary to include actions and next steps. This would be fed into the outcomes of future reports.
- 69.3. **Council noted the discussions from the workshop.**

70. Actions and matters arising

- 70.1. Three actions were outstanding. At 31.6., the report on equality, diversity and inclusion in fitness to practise processes would be commissioned externally. This would go out to tender early next year and would probably come to a Council meeting in autumn 2018.
- 70.2. At 58.2., a table comparing GPhC and the Care Quality Commission (CQC) powers would come to Council as part of a discussion on the development of future inspection in 2018.
- 70.3. The action at 59.9., a paper to Council about wider data and policy issues around the Registration Assessment, would come to Council by June 2018.

71. Review of statutory committee competences

- 71.1. Elaine Mulingani (EM) introduced Elisabeth Davis (ED), the Chair of the Appointments Committee, who presented **17.12.C.01** to Council. This paper proposed changes to statutory member competencies prior to the 2018 new member recruitment programme.
- 71.2. The team were looking to take on about 18 new members in the next round of recruitment including registrant panel members, chairs and deputy chairs.
- 71.3. Members checked that the requirement for legally qualified chairs would remain; ED assured them that this would now be one of the essential criteria in the job description at the start of the recruitment process.
- 71.4. Under 1. Intellectual capacity, in Appendix 1, members discussed how realistic it was to demand of registrant members that they *'maintain a general awareness of issues across all sectors of pharmacy practice'*. ED clarified that what was important was that the applicants demonstrated their ability to apply their knowledge of the profession elsewhere after members expressed their concern that it may be off putting to suitable applicants. It was agreed to amend the sentence to *'across a wider variety of sectors'*.
- 71.5. The Nolan Principles of Public Life needed to be updated to those of the Committee of Standards in Public life. Members asked whether a principle regarding respect could be

included. ED said that this could be incorporated into the working style and communication section.

- 71.6. **Council agreed the recommendation from the Appointments Committee to amend the competencies, with the suggested amendments, for statutory committee members as per the draft at Appendix 1.**

72. Promoting professionalism, reforming regulation (Department of Health consultation)

- 72.1. Priya Warner (PW) and Osama Ammar (OA) presented paper **17.12.C.02**, which provided Council with an opportunity to discuss the Reforming Regulation, Promoting Professionalism consultation and the organisation's approach to responding to this.
- 72.2. The Chair asked for more information about next steps as far as Council were concerned. PW explained that a response would be drafted and circulated to members later that month for their comments. The deadline for submitting the response to the Department of Health was the 23 January. The final response would be brought to the next Council meeting in February for noting.
- 72.3. **Council discussed the paper.**

73. Response to the consultation on revalidation for pharmacy professionals

- 73.1. OA presented paper **17.12.C.03** which provided Council with an opportunity to review and approve the draft framework for revalidation for pharmacy professionals before it was implemented. Council were also asked to formally agree a number of matters that made the communication of the framework and its requirements easier for registrants as these matters related to specific requirements in the Pharmacy Order 2010.
- 73.2. Samantha Quaye declared an interest as a registrant and an employee of a training provider that would be helping registrants to complete the revalidation process. Digby Emson, Berwyn Owen, Mohammed Hussain, Elizabeth Mailey and Jo Kember declared an interest as registrant members.
- 73.3. Members sought assurance that the resources and communications would be in place for such a big change. OA said that they had not underestimated the challenge; more work would be undertaken with other pharmacy organisations in the coming months.
- 73.4. Council also discussed what could be done in terms of preparing undergraduates and those in pre-registration for revalidation once they were on the Register. Other areas of the organisation's work would assist in developing necessary skills.
- 73.5. OA confirmed that initially evaluation of the new framework would be internally conducted, becoming independent as it was more established.

- 73.6. Employers' support would be gained in part by regulatory levers supporting revalidation, in the standards for registered pharmacies, for example. The challenge would include supporting registrants in settings that were not regulated by the GPhC, as well as those working in registered pharmacies. Duncan Rudkin (DR) explained that there was work to be done in articulating how regulatory processes supported one another. Links to supporting revalidation should be explicit in guidance and standards, providing clarity that enabling registrants to complete the revalidation process was integral to running a registered premises or being a professional.
- 73.7. Members also pointed out that registrants would need the support of pharmacy organisations in engaging with the revalidation process. Thus far they had been very helpful; it was important that they remained engaged and were kept well informed of the benefits of their continued involvement.
- 73.8. The smooth and correct operation of the portal through which revalidation would be submitted was highlighted as a reputational risk should it not function properly. OA assured members that checks had been built in to the development programme and that risk management processes were in place.
- 73.9. Members asked for more information on groups less likely to engage. Support would be available to them in the revalidation guidance materials and from other pharmacy organisations that the GPhC were working with.
- 73.10. Clarification was sought at page 26 of the document where it stated, 'The review will be carried out jointly by a pharmacy professional and a lay reviewer.' A question was raised on sectoral experience and it was agreed that the framework should enable flexibility around matching reviewers' experience and background with those of the registrants under review.
- 73.11. Council discussed whether there were any lessons to be learnt from other regulators' implementation of their revalidation processes. It was agreed that it was hard to predict any impact on renewal rates, however there were some assurances provided:
- There had been a mandatory CPD requirement to be on the Register for a long time.
 - Activities included in revalidation were accessible, achievable and already occurring in registrants' practise and they were used to completing it.
 - Reasons for non-renewal would be monitored to pick up whether the revalidation process was one of them.
- 73.12. DR reminded Council that they had always been very clear that rather than trying to identify those with potential issues around their fitness to practise, the revalidation process was about supporting development and improvements using a reflective approach to learning.

- 73.13. There was some discussion around the implementation timetable. Members discussed whether to stagger implementing the peer discussion element of revalidation by a year to give registrants more time to develop their skills in this area and complete some quality assurance around it. It was agreed that communications needed to be very clear on timings and that they would be in the right order.
- 73.14. Following discussion Council agreed that they would not stagger introducing the different elements of revalidation, but that they would want to be kept updated with any issues and receive a review of the process after a year.
- 73.15. **Council:**
- i. **Agreed the response and the revalidation framework**
 - ii. **Agreed the implementation timetable**

74. Rebalancing programme board update

- 74.1. DR presented **17.12.C.04**. This paper provided Council with an update of the work of the Rebalancing Programme Board and the role of the GPhC on the board.
- 74.2. DR clarified that at para 2.4 'Professional organisations have been asked to canvas for views received' meant only that and was not a replacement for consultation.
- 74.3. When the consultation was launched there would be conversations about sequencing, a lot of work would need to be carried out in policy development and deciding where and how best to engage.
- 74.4. This would need to be developed in line with the work on education – so the fact that they had been linked in the organisational re-structure made sense.
- 74.5. De-criminalisation of dispensing errors would encourage transparency. A greater reporting culture was being encouraged which would ultimately lead to safer care. It continued to be important for the GPhC to be clear about its role, and that of other organisations, in relation to this agenda.
- 74.6. Members discussed how inspection could be used as part of an assurance mechanism for the public. Our regular inspections made sure that systems and processes were in place and being followed. The introduction of themed inspections would gather insights for wider learning.
- 74.7. **Council noted the paper.**

75. Update: Implementing new education and training standards for pharmacy technicians

- 75.1. Damian Day (DD) presented paper **17.12.C.05**, which provided Council with an update on plans for implementing new standards for the education and training of pharmacy technicians.
- 75.2. Members' attention was drawn to 2.2 where it was stated that the organisation was ready to accredit new courses as a priority.
- 75.3. Digby Emson declared an interest in this item as a registrant and the chair of a training provider. Samantha Quaye declared an interest as a pharmacy technician and an employee of a training provider for postgraduates in pharmacy. Berwyn Owen, Mohammed Hussain, Evelyn McPhail, Elizabeth Mailey and Jo Kember declared an interest as registrant members.
- 75.4. There was some challenge from Council in allowing 'trailblazers' to accept qualifications for pharmacy technicians based on previous standards until new qualifications based on our most recent set of standards were approved. DD explained that this may put funding at risk as if a trailblazer was not agreed with the Institute for Apprenticeships (IfA), public funding for the training may cease and trainees that could not fund themselves or secure sponsorship would be unable to train.
- 75.5. Members agreed that qualifications should be under the new standards; as the regulator we would ask that the IfA were committed to developing quality. DD said that funding continuity had been assured and that using the old standards would only be a transitional measure.
- 75.6. **Council noted the current position regarding the implementation of new standards for the education and training of pharmacy technicians.**

76. Annual plan progress report

- 76.1. Megan Forbes (MF) presented **17.12.C.06**. This paper reported to Council on the progress against the annual plan to the end of September 2017.
- 76.2. Members welcomed the report and its honesty about the challenges facing the organisation. They found the new format helpful.
- 76.3. Members discussed the risks of legal challenge around the inspection reports. Claire Bryce-Smith (CBS) explained that the new style of report was in development and was currently being reviewed by patient focus groups.
- 76.4. It was agreed that there would be scope for working with other organisations in sharing data insights.

- 76.5. Council asked what the timetable was for reviewing the scope of the data and insight development project. They felt that they should see a project plan of deliverables and how they would fit in with the budget with benefits and investment costs identified. There was a lot of work scheduled for January to March 2018 and members sought assurance that this was realistic.
- 76.6. CBS told members that an outline plan of work streams would be going to the Audit and Risk Committee at their meeting in January. This was a period of consolidation including recommendations from the committee and some internal factors such as infrastructure and capacity.
- 76.7. MF said that the benefits of Transformation would be added to the plan. Specific project benefits of Casetracker and online registration would come to the Efficiency and Effectiveness Assurance and Advisory Group (EEAAG) meeting in May 2018.
- 76.8. It was likely that some of the large amount of work scheduled for early 2018 would overrun, however significant steps would have been made.
- 76.9. Council sought explicit assurance that the IT portals were unlikely to fail under high demand and had been thoroughly tested. MF confirmed that this was the case and said that there was a very low tolerance of risk in this area.
- 76.10. Members felt that the report should reflect more on the progress that had been made in the organisation's restructure.
- 76.11. **Council noted and commented on the report on progress against the annual plan.**

77. Audit and Risk Committee, unconfirmed minutes of the meeting on 25 October 2017

- 77.1. Digby Emson (DE) as Chair of the Audit and Risk Committee presented **17.12.C.07**. The meeting in October had been challenging in that there had been requests for delays on some internal audit reports. The Committee had considered these in detail and felt that these reflected the fact that the organisation had been over ambitious in its targets and had more work to do on improving data quality.
- 77.2. Following the appointment of the Director of Insight, Intelligence and Inspection and assurance that a thorough review of outstanding actions would come to the Committee's meeting in January, DE reported that the Committee did feel somewhat assured that progress would be made.
- 77.3. The completed internal audit reports were rated at either amber or green/amber. The Committee were concerned at this and in one instance would receive an interim review of the process to be able to assess any improvement.
- 77.4. Council supported the Committee in following through on the actions and reviews that had been agreed to. They looked forward to discussions around risk at their next meeting.

- 77.5. DR said that he shared the Committee's concerns. He would ask that they be seen in the context of a number of challenges. There had been cultural issues within the organisation on accountability, timetables had not been thought out properly and management processes had been disconnected from the internal audit process.
- 77.6. Day to day business needed to be better integrated with the Audit and Risk Committee's planning of internal audit. This would happen over the next year as the disconnect was mended and audit follow up would be put in its proper context. Members offered their support on this.
- 77.7. **Council noted the unconfirmed minutes of the Audit and Risk Committee meeting.**

78. Any other public business

- 78.1. There being no further public business to discuss the meeting closed at 15:45.

Date of the next meeting:

Thursday 8 February 2017

Meeting paper

Council on Thursday, 08 February 2018

Public business

Council Workshop Summary

Purpose

To provide an outline note of the discussions at the December Council workshop

Recommendations

The Council is asked to note the discussions from the workshop

1. Introduction

- 1.1. The Council holds a workshop session alongside its regular Council meetings each month (there are no meetings in January and August). The workshops give Council members the opportunity to:
 - interact with and gain insights from staff responsible for delivering regulatory functions and projects;
 - receive information on projects during the development stages;
 - provide guidance on the direction of travel for work streams via feedback from group work or plenary discussion; and
 - receive training and other updates.
- 1.2. Following each workshop there will be a summary of the discussions that took place, presented at the subsequent meeting. This will make the development process of our work streams more visible to the GPhC's stakeholders. Some confidential items may not be reported on in full.
- 1.3. In the workshop sessions the Council does not make decisions. The sessions are informal discussions to aid the development of the Council's views.

2. Summary of December's workshop -

2.1. *Reform of regulation*

The Council had a workshop on the government's consultation, Promoting Professionalism, Reforming Regulation. They considered the different areas of consultation and principles for the GPhC's response.

Following the workshop Council members received a draft for comments. The final version was submitted to the Department of Health in January. A paper is tabled for this meeting explaining the process and sharing the final response.

2.2. *Budget 2018/19*

The Council received a presentation on the approach being taken in relation to business planning and budgeting. It was explained that the timetable for our work on the budget was different from previous years, due in part to the structural changes amongst the senior leadership team. Early draft figures were presented which needed to go through a further challenge process.

The next stage of developing the work would be presented to the Efficiency and Effectiveness Assurance and Advisory Group in January before coming to the full Council meeting in March.

2.3. *Fitness to practise data analysis*

The Council received a presentation on fitness to practise data. Some emerging themes and trends were identified. Members were asked what other information they would like to see, whether they had any questions that they would like answered and how this could be communicated most effectively.

The information gathered at this workshop would feed into work on categorisation, on improving consistency in how information was recorded and identifying questions that most needed answering.

2.4. *Update on independent prescribers*

Members had a workshop on preparing to consult on the standards for the education and training of pharmacist independent prescribers. They considered the scope of the consultation, and which safeguards should be put in place.

The work done at this workshop fed into the consultation which is on the agenda for approval at this meeting.

Recommendations

Council is asked to note the discussions from the workshop

Duncan Rudkin, Chief Executive and Registrar
General Pharmaceutical Council

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31 January 2018

Council actions log

| Meeting date | Ref. | Action | Owner | Due date | Status | Comments/update |
|--------------|------|---|--------------------|----------|--------|---|
| 6 Jul 2017 | 31.6 | Consultation on revised threshold criteria: A report on equality, diversity and inclusion in Fitness to Practise processes would be brought to Council in due course. | Claire Bryce-Smith | Sep 18 | Open | This report will be commissioned externally and will go out to tender in Jan/Feb 18. It is anticipated that it will take at least three months to produce the report. |
| 9 Nov 2017 | 58.2 | Actions and matters arising: Council asked for a brief comparative table of GPhC and Care Quality Commission (CQC) powers regarding premises, owners and businesses. | Duncan Rudkin | Jun 18 | Open | The table will be included in briefing material for a future Council discussion on the development of inspection, in 2018 |
| | 59.9 | Registration assessment and Board of Assessors' Report – June and September 2017: Wider data and policy issues around the Registration Assessment would be picked up in a paper to Council from the executive, out of the current reporting cycle. | Mark Voce | Jun 18 | Open | |

Meeting paper

Council on Thursday, 08 February 2018

Public business

Performance Monitoring and Annual Plan Progress Report

Purpose

To report to Council on operational and financial performance and progress against the annual plan from September to December 2017

Recommendations

The Council is asked to note and comment on:

- i. the performance information provided at appendix 1; and
- ii. the report on progress against the annual plan at appendix 2.

1. Introduction

- 1.1. This paper reports on operational and financial performance and progress against the annual plan (year one of the business plan 2017-2020), as part of our new business report.
- 1.2. The first of these reports was presented to Council in September 2017, covering Quarter 1 from April to June 2017. Whilst Quarter 2, July to September 2017, saw a de-coupling of the Performance Monitoring Report (PMR) and Annual Plan Progress report updates as part of an administrative oversight, this report aligns them again with reporting on Quarter 3, September to December 2017.
- 1.3. The sections below provide an executive summary of key areas to note within the report.

2. Customer services

- 2.1. During the quarter, the two telephone contact centre KPIs were missed, with the performance improving compared to the previous quarter. The KPI for the email correspondence was met and showed continued improvement for the third consecutive quarter with 99.6% of emails actioned within 2 days.
- 2.2. Recruitment is continuing in order to complete the team. This is designed to improve performance and prepare for future challenges as the team addresses transformation initiatives.

3. Fitness to Practise

- 3.1 The number of concerns received has again increased during this quarter. For the first time, the average number of concerns received each month exceeded 200. Despite this increase, the number of stream 1 cases closed, and the number of stream 2 cases closed or referred to the Investigating Committee at the end of the investigation, increased over the quarter.
- 3.2 During this quarter, we introduced a new KPI for triage, of 5 days. We did this because, due to unfilled vacancies and staff sickness, only one (out of five) triage officers was working for a considerable period. This staff shortage coincided with a marked increase in the number of concerns received, which meant that it was unrealistic for cases to be triaged properly within three days.

4. Inspection

- 4.1 The number of pharmacies not inspected for 36 months or more has decreased for the fourth quarter in succession from 3,493 to 3,216. As forecast, with the exception of the annual dip in December, we have continued to complete in excess of 300 inspections per month and in excess of 900 inspections this quarter to keep on top of the flow of pharmacies through the age categories. At the cut-off point for this performance report, one pharmacy had entered the +60 months category, which has now been inspected.
- 4.2 With our overall productivity we expect to maintain a 54 month maximum. However, this will vary month-by-month due to previous historical spikes in particular geographical areas. In this quarter, the number of pharmacies not inspected for +54 months increased to 181. Each inspector continues to focus on the pharmacies in their particular area which have not been inspected for the longest period.

5. Human Resources













- 5.1 The total number of leavers for this period was 10 permanent employees, reducing the headcount to 233. The turnover rate for permanent staff excludes those employees who were/are on a fixed term contract.
- 5.2 The total number of permanent leavers for this specific period equates to a turnover rate of 18.2%, however the year to date turnover rate is currently 14.9% due to fewer leavers in 2017 than 2016. The year to date 2017 figure is favourable when compared to the overall turnover rate of 20.9% for the whole of 2016.

6. Finance

- 6.1 The year to date position for the organisation overall is a positive variance of £229K against the forecast including interest and tax.

7. Annual plan progress report

- 7.1. Appendix 2 on progress against the annual plan 2017/18 covers Quarter 3 from September to December 2017. The six key work streams reported are set out below with indicators of their current state of progress against the business plan aims:

| Programmes of work | Status | Direction of travel |
|--|---|---|
| Developing our approach to regulating registered pharmacies to provide assurance and encourage improvement |  |  |
| Promoting professionalism through the standards for pharmacy professionals and related guidance |  |  |
| Providing further assurance to the public that pharmacy professionals are meeting the standards |  |  |
| Setting the standards and quality assuring the initial education and training for pharmacists and pharmacy technicians |  |  |
| Developing our data and insight strategy |  |  |
| Transforming our services and the way we work |  |  |

- 7.2. Following on from the last review period, we've continued to provide further transparency on how we are progressing against the timetable we set ourselves for the business plan year; where we are proceeding in accordance with that timetable; where we are falling behind or where we might be ahead of where we thought we would be. Further explanation with regards to the timetable is provided in the commentary.
- 7.3. The two work streams which reported as 'green' in the last report (promoting professionalism through the standards for pharmacy professionals and related guidance; and providing further assurance to the public that pharmacy professionals are meeting the standards) remain green. Three which previously reported as 'amber' remain at amber (developing our approach to regulating registered pharmacies; setting the standards and quality assuring the initial education and training for pharmacists and pharmacy technicians; and transforming our services and the way we work). On workstream which previously reported as 'red' (developing our data and insight strategy) now reports at amber because a forward plan to establish our strategy has been presented to the Audit and Risk Committee and was supported.
- 7.4. Council will note that in previous progress reports we have stated that in order to challenge ourselves in our planning, we are progressively introducing specific success measures going forwards. Whilst we have made improvements in our planning and reporting at all levels and across the organisation, we acknowledge that progress in developing success measures has been limited. This will be an area of particular focus in year two of the Business Plan 2017-20.

7.5. In addition to reporting to Council in relation to efficiency and effectiveness we report to the Efficiency and Effectiveness Assurance and Advisory Group (EEAAG) on a quarterly basis, with a particular emphasis on transformation work.

7.6 As highlighted with the last progress report, an internal Performance and Delivery Board has been established, with a pilot stage now extended to February 2018. This monitors and reports on our progress for the main pieces of work to deliver our Business Plan as well as monitoring and reporting on the performance of our regulatory functions. It is chaired by the Deputy Chief Executive with Directors as members. The Performance and Delivery Board has the following aims:

- Monitor the performance of regulatory functions to the levels set out in the business report KPIs
- Monitor the achievement of the business and directorate plans in line with the agreed milestones and key dates
- Identify where performance is not adequate and ensure that actions are taken to remedy performance within an agreed timeframe
- Provide context, narrative and analysis for the business report and quarterly cycle of reporting

8. Equality and diversity implications

8.1. Equality, Diversity & Inclusion objectives and commentary are included as part of each work stream in the Annual Plan Progress Report.

9. Communications

9.1. 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 website, wider communications through the media and directly 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.

10.Resource implications

10.1. Resource implications are addressed within the report.

11.Risk implications

- 11.1. Failure to maintain an accurate register and/or carry out our other regulatory functions efficiently and effectively could have implications on patient safety, and a significant impact on the GPhC's reputation.
- 11.2. 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.

12. Monitoring and review

- 12.1. Council will receive a performance monitoring and annual plan progress report on a quarterly basis, providing an update of the delivery of the GPhC's regulatory functions, finances and progress against the annual plan.
- 12.2 As highlighted previously in the paper, updates will also be received by the Efficiency and Effectiveness Assurance and Advisory Group, as well as the Performance and Delivery Board.

Recommendations

The Council is asked to note and comment on:

- i. the performance information provided at appendix 1; and
- ii. the report on progress against the annual plan at appendix 2

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General Pharmaceutical Council

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Performance Monitoring Report: end December 2017

1. Customer services

1.1 Registrations

| | Route to Register | 2016/17 | | | 2017/18 | | |
|-----------------------|-------------------|---------|-----|-----|---------|-------|-----|
| | | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 |
| Pharmacists | Total | 2,800 | 611 | 153 | 94 | 2,321 | 597 |
| | UK | 2,640 | 437 | 136 | 60 | 2,260 | 561 |
| | EEA | 102 | 160 | 11 | 30 | 20 | 22 |
| | Non-EU/EEA | 58 | 14 | 6 | 4 | 41 | 14 |
| Pharmacy technicians | Total | 441 | 365 | 239 | 194 | 350 | 441 |
| | UK | 434 | 360 | 232 | 191 | 343 | 438 |
| | EEA | 5 | 4 | 7 | 3 | 5 | 2 |
| | Non-EU/EEA | 2 | 1 | | | 2 | 1 |
| Registered pharmacies | | 88 | 61 | 74 | 127 | 102 | 79 |

Includes new joiners and restorations up to 31st December 2017

The number of new pharmacists joining the register in Q3 relates to the successful candidates who passed the autumn registration assessment. In addition, the number of pharmacy technicians joining the register is traditionally high at this time of year, as they complete their training cycle. The number of new EEA registrations continues to be impacted by the introduction of English language requirements and Brexit.

1.2 Registration Totals

| | Total | Budgeted | Variance |
|-----------------------|--------------|-----------------|-----------------|
| Pharmacists | 55,960 | 56,328 | -368 |
| Pharmacy technicians | 23,600 | 23,613 | -13 |
| Registered pharmacies | 14,417 | 14,272 | 145 |

Register totals as at 31st December 2017

1.3 Median application processing times for pharmacists

| Median application processing times for pharmacists (working days) | | Median application processing times for pharmacy technicians (working days) | |
|---|----|--|---|
| Application receipt to approval | 2 | Application receipt to approval | 0 |
| Application receipt to entry | 15 | Application receipt to entry | 7 |

Medians calculated for applications during the period 1 October 2017 to 31st December 2017

The difference between the two status measurements for each registrant type relates to the current dual entry point each month onto the Register.

1.4 Contact Centre

| Phone | 2016/17 | | | 2017/18 | | |
|--|---------|--------|-------|---------|--------|--------|
| | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 |
| Calls made to GPhC | 18,539 | 13,081 | 9,176 | 14,024 | 17,131 | 11,968 |
| Calls answered within 20 seconds (KPI > 80%) | 73.6% | 60.0% | 62.6% | 49.0% | 67.5% | 71.3% |
| Calls abandoned (KPI < 5%) | 4.0% | 9.8% | 9.0% | 11.8% | 5.8% | 5.9% |
| Correspondence | | | | | | |
| Emails actioned within 2 days (KPI > 90%) | 92.6% | 80.0% | 89.3% | 98.6% | 97.3% | 99.6% |

Calls and emails typically reduce after the busy summer period however with the main deadline for renewals on 31st October 2017 much of the call volumes were driven by queries associated with late payers and final removal letters being issued before Christmas. This also coincides with registration assessment results being released at the end of October and then main registration period for the successful candidates starting from 1st November adding to much of the daily traffic.

Call abandonment rate remained consistent with Q2 however still remains marginally outside the KPI target of 5% over the quarter. Calls answered with 20 seconds have shown improvement over the previous quarter despite remaining outside the 80% KPI target. 99.6% of emails were actioned within 48 hours of receipt with only 16 emails missing the deadline.

Recruitment is continuing in order to complete the team. This is designed to improve performance and prepare for future challenges as the team addresses transformation initiatives.

1.5 Continuing Professional Development

| Call and submission data | | 2014-15 Call | 2016 Call (2.5% sample pilot) | 2017 Call |
|---|---------------------------------|----------------|-------------------------------|--------------|
| | Records requested | 19,197 | 1798 | 1544 |
| | Submitted by deadline | 17,802 (92.7%) | 1,687 (93.8%) | 1418 (91.8%) |
| Submission issues | | | | |
| Extensions | Extensions granted | 450 (2.3%) | 58 (3.2%) | 36 (2.3%) |
| Incomplete ¹ | Incomplete records | 1,400 (7.3%) | 145 (8.1%) | 117 (7.6%) |
| Problems ² | Problem submissions | 17 (0.1%) | 0 | 0 |
| Non-compliance action | | | | |
| Reminders | 1st reminder | 1,160 (6.0%) | 1454 (80.9%) | 680 (44%) |
| | 2nd reminder | 687 (3.5%) | 111 (6.2%) | 388 (25.1%) |
| Remediation | Entered into remediation | 137 (0.7%) | 253 (14.1%) | 55 (3.6%) |
| Removal process | Notice of intention to remove | 407 (2.1%) | 182 (10.1%) | 90 (5.8%) |
| | Notice of removal | 213 (1.1%) | 52 (2.9%) | 39 (2.5%) |
| Overall compliance | | | | |
| Met requirements at 1 st attempt | | 19,027 (99.9%) | 1451 (80.7%) | 1447 (93.7%) |
| Met requirements at 2 nd attempt | | | 246 (13.7%) | 45 (2.9%) |
| Removal for non-compliance | | 170 (0.9%) | 25 (1.4%) | 21 (1.4%) |
| Removal from call | Voluntary removal from register | 0 (0.0%) | 23 (1.3%) | 21 (1.4%) |
| | Deleted from register | | 1 (0.1%) | 0 |
| | Failed to renew registration | | 10 (0.5%) | 3 (0.2%) |
| | CFtP pilot participation | | 6 (0.3%) | 0 |
| Pending | | 0 (0.0%) | 1 (0.05%) | 0 |
| Overall compliance rating | | 19,027 (99.9%) | 1697 (94.4%) | 1498 (97%) |

About the data

Figures are presented as annual call cycles. 2014-15 calls commenced in October 2014 and ended in June 2015. The 2016 and 2017 calls use a sampling approach of 2.5% of the professional registers.

The 2017 call has now drawn to a close with no pending registrants.

*Data was extracted on **22nd January 2018.***

Commentary

¹ Incomplete refers to having approval to submit fewer entries than usually required (9 per year) as a result of periods away from practice, such as parental or sick leave.

² Problem submissions are those that are submitted in formats that cannot be accepted and therefore it is not possible to process them.

2. Fitness to Practise (FtP)

2.1 Fitness to Practise performance standards

| | | 2016/17 | | 2017/2018 | | |
|--|-----|---------|-------|-----------|-------|-------|
| | | Q3 | Q4 | Q1 | Q2 | Q3 |
| All cases triaged during this period | No. | 458 | 507 | 462 | 563 | 602 |
| Of which cases triaged within 3 working days | No. | 391 | 487 | 458 | 540 | 381 |
| | % | 85.4% | 96.1% | 99.1% | 95.9% | 63.3% |
| Of which cases triaged within 5 working days | No | | | | | 532 |
| | % | | | | | 88.4% |

Cases closed 1 October 2017 to 31 December 2017, which may have been opened at any time.

| | | 2016/17 | | 2017/2018 | | |
|---|-----|---------|-------|-----------|-------|-------|
| | | Q3 | Q4 | Q1 | Q2 | Q3 |
| All stream 1 cases closed pre-IC | No. | 154 | 182 | 148 | 153 | 212 |
| Of which closed within 3 months | No. | 127 | 161 | 138 | 127 | 177 |
| | % | 82.5% | 88.5% | 93.2% | 83.0% | 83.9% |
| All stream 2 cases closed pre-IC or referred to the IC[1] | No. | 161 | 203 | 157 | 123 | 179 |
| Of which closed or referred within 10 months | No. | 110 | 123 | 131 | 106 | 148 |
| | % | 68.3% | 60.6% | 83.4% | 86.2% | 82.7% |
| All cases closed or referred at IC | No. | 44 | 43 | 53 | 36 | 17 |
| Of which reach IC within 12 months | No. | 19 | 15 | 18 | 16 | 13 |
| | % | 43.0% | 34.9% | 34.0% | 44.4% | 84.6% |
| All FTP committee cases closed | No. | 24 | 18 | 29 | 31 | 19 |
| Of which closed within 24 months | No. | 11 | 10 | 18 | 16 | 14 |
| | % | 45.8% | 55.5% | 62.1% | 51.6% | 73.7% |

The number of concerns received has again increased during this quarter. For the first time, the average number of concerns received each month exceeded 200. Despite this increase, the number of stream 1 cases closed, and the number of stream 2 cases closed or referred to the Investigating Committee at the end of the investigation, increased over the quarter.

During this quarter, we introduced a new KPI for triage, of 5 days. We did this because, due to unfilled vacancies and staff sickness, only one (out of five) triage officers was working for a considerable period. This staff shortage coincided with a marked increase in the number of concerns received, which meant that it was unrealistic for cases properly to be triaged within three days.

2.2 Caseload age profile

| Age profile | | 2016/17 | | 2017/18 | | |
|------------------------|-----|---------|--------|---------|--------|--------|
| | | Q3 | Q4 | Q1 | Q2 | Q3 |
| Under 6 months | No. | 343 | 384 | 375 | 447 | 443 |
| | % | 57.2% | 56.0% | 57.4% | 58.3% | 58.8% |
| 6-12 months | No. | 100 | 141 | 130 | 177 | 157 |
| | % | 15.5% | 20.6% | 19.9% | 23.1% | 20.9% |
| 12-14 months | No. | 61 | 30 | 32 | 24 | 30 |
| | % | 9.5% | 4.4% | 4.9% | 3.1% | 4.0% |
| 15 months old and over | No. | 116 | 130 | 116 | 119 | 123 |
| | % | 17.9% | 19.0% | 17.8% | 15.5% | 16.3% |
| Total | No. | 659 | 685 | 653 | 767 | 753 |
| | % | 100.0% | 100.0% | 100.0% | 100.0% | 100.0% |

As can be seen in paragraph 2.1 above, there was a further, significant, increase in the number of concerns received in this quarter. Despite this increase, the number of open cases has reduced slightly. This is because we have continued to work hard to close cases at the appropriate point in the fitness to practise process. The number of cases aged over 12 months has increased during this quarter, but, as can be seen from paragraph 2.4, there has been a reduction in the number of our oldest cases, aged 20 months and older. This is a result of our continued strategy of focussing on closing our oldest cases.

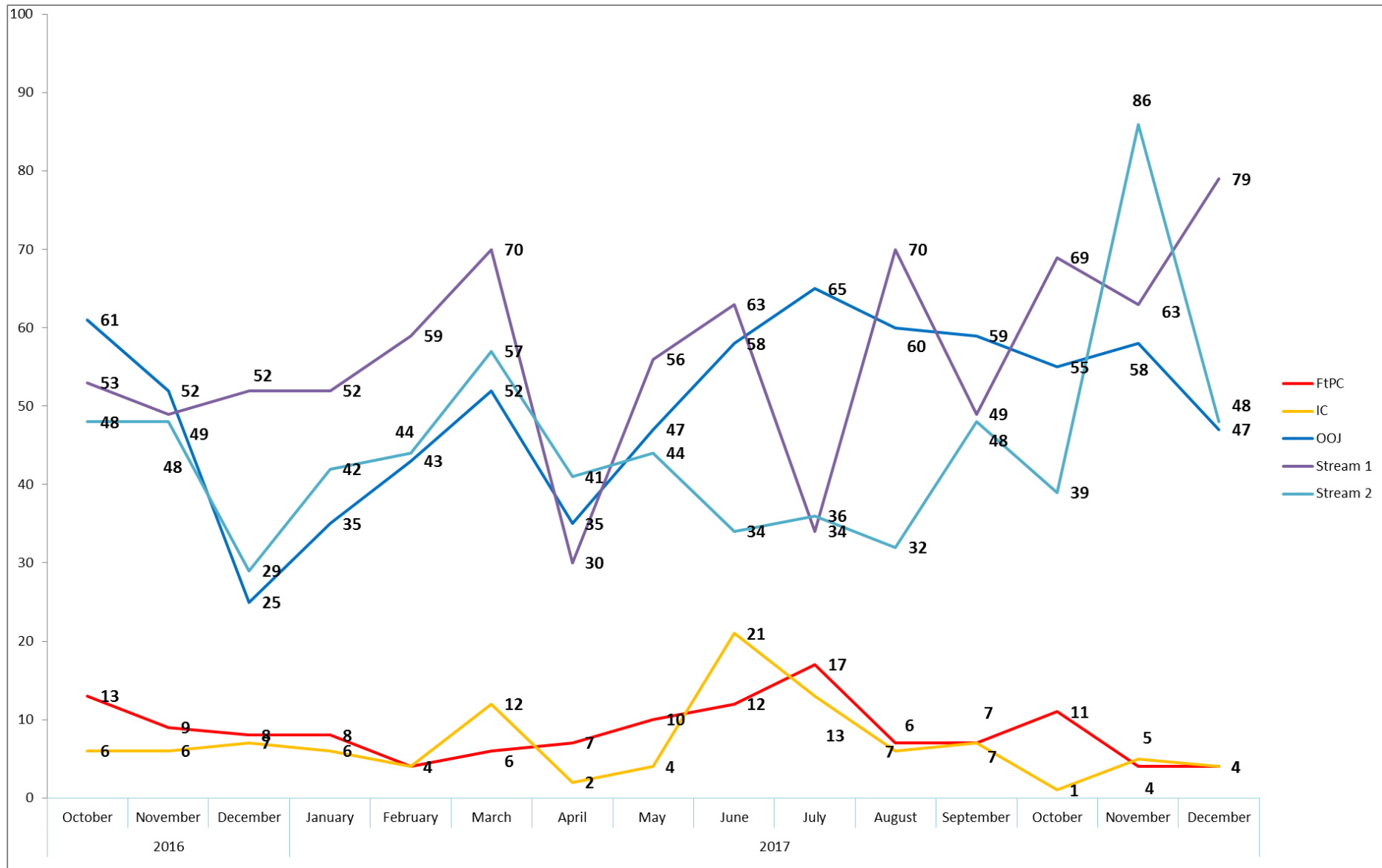
2.3 Cases over 15 months

| Age profile | | 2016/17 | | 2017/18 | | |
|-------------------|-----|---------|-------|---------|-------|-------|
| | | Q3 | Q4 | Q1 | Q2 | Q3 |
| 15-19 months | No. | 47 | 52 | 46 | 48 | 67 |
| | % | 40.5% | 40.0% | 39.7% | 40.3% | 54.5% |
| 20-24 months | No. | 34 | 44 | 30 | 29 | 17 |
| | % | 29.3% | 33.8% | 25.9% | 24.4% | 13.8% |
| 25-29 months | No. | 10 | 15 | 23 | 17 | 20 |
| | % | 8.6% | 11.5% | 19.8% | 14.3% | 16.3% |
| 30-34 months | No. | 10 | 7 | 6 | 11 | 10 |
| | % | 8.6% | 5.4% | 5.2% | 9.2% | 8.1% |
| 35-39 months | No. | 7 | 4 | 5 | 6 | 4 |
| | % | 6.0% | 3.1% | 4.3% | 5.1% | 3.3% |
| 40-42 months | No. | 2 | 4 | 1 | 2 | 2 |
| | % | 1.7% | 3.1% | 0.9% | 1.6% | 1.6% |
| 43-49 months | No. | 4 | 3 | 4 | 6 | 2 |
| | % | 3.4% | 2.3% | 3.4% | 5.1% | 1.6% |
| 50 months or more | No. | 2 | 1 | 1 | 0 | 1 |
| | % | 1.7% | 0.8% | 0.9% | 0.0% | 0.8% |

The number of cases aged over 15 months has increased slightly during this quarter. This increase was caused by a large number of cases moving into the 15 to 19 months category. The number of cases aged over 19 months has gone down. This change was a result of our focus on closing our oldest open cases.

One open case has been opened for more than 50 months. The principal hearing before the Fitness to Practise Committee was listed twice in 2017. The first hearing was postponed because of an application for disclosure from the registrant, which was detailed very close to the date of the hearing. The second hearing was adjourned part-way through because the chair of the panel considering the case resigned. The Chair of the Fitness to Practise Committee determined that the hearing needed to start again from the beginning. It is anticipated that the hearing will be relisted, and finish, within quarter four.

2.4 Cases closed by stage



2.5 DBS referrals

The GPhC's Disclosure and Barring Service (DBS) and Disclosure Scotland (DS) Referrals Panel considered 4 matters during this quarter, of which none was referred to DBS (covering England and Wales) and one was referred to DS. The decision to refer was taken at the end of this quarter, although the referral was not made until the beginning of the following quarter.

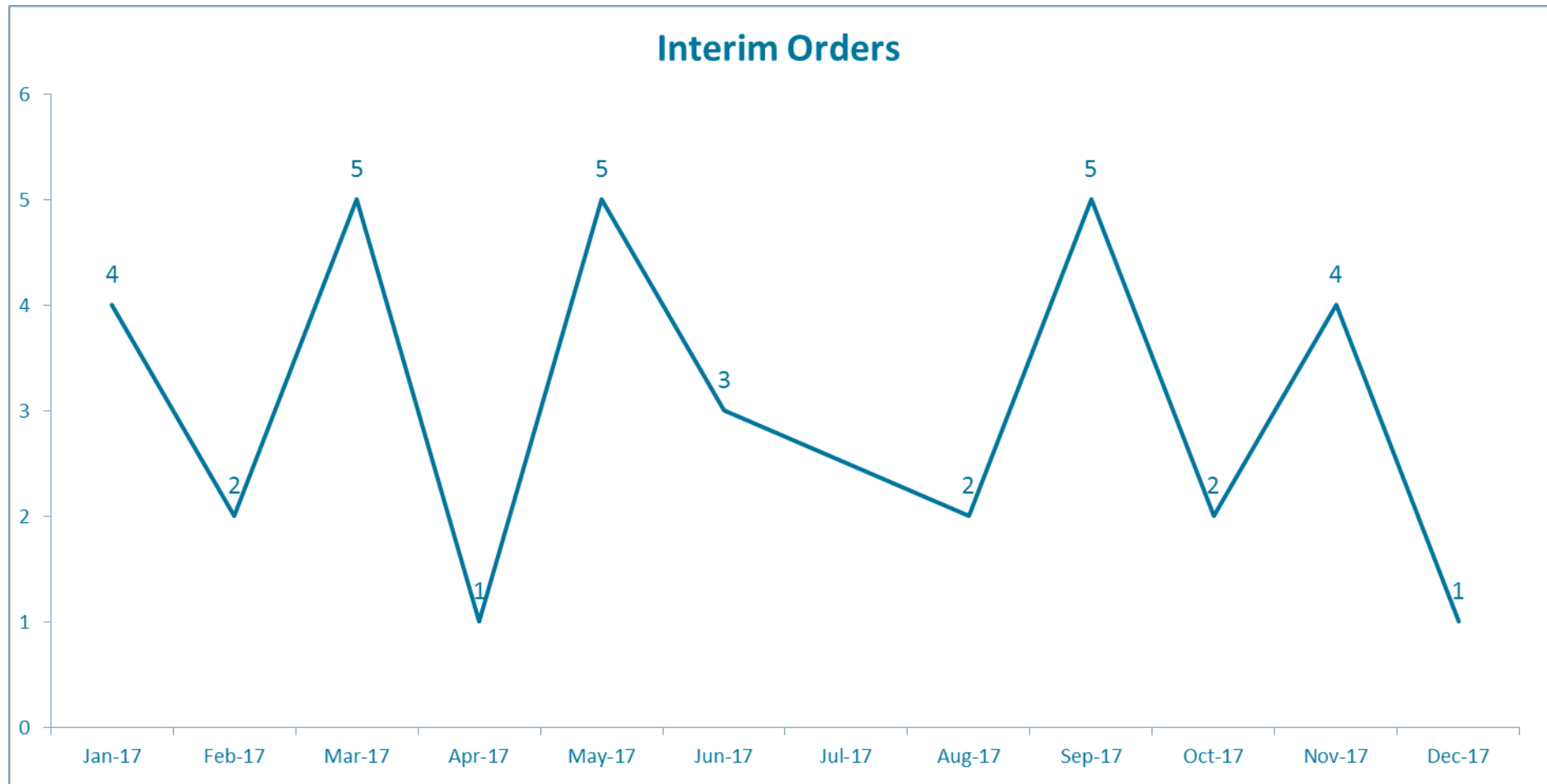
2.6 Appeals

One new appeal was brought by a registrant during this quarter. This appeal is ongoing. The appeals brought by two registrants (joined as one case) ended during this quarter. The registrants' appeals failed and the decision of the Fitness to Practise Committee was upheld. At the end of the quarter, there was one additional, ongoing, appeal, before the Court of Appeal, which was subject to a reserved judgment. Since the end of this quarter, judgment has been given. The registrant's appeal failed, and the decision of the Fitness to Practise Committee was upheld.

2.7 Interim Orders

The Fitness to Practise Committee imposed 8 new interim orders during this quarter. No applications were refused, and one was adjourned. Our main timeliness target for interim order applications is the amount of time taken between receiving enough information to justify applying for an interim order, and the date of the application hearing before the Fitness to Practise Committee. During this quarter, the median period for this stage reduced from 2.1 weeks to 1.9 weeks. This is particularly heartening because there is built into this period a week's notice to the registrant of the hearing. Accordingly, the internal decision-making process to determine whether or not to apply for an interim order took a median of 0.9 weeks.

2.8 Interim Orders



FtPC made 7 new interim orders; improving on the median time of committee decision from 2.1 to 1.9 weeks over the previous 12 months.

3. Inspection

3.1 Inspections undertaken

| | Routine inspections | Follow up inspections | Visits before registration |
|------------|---------------------|-----------------------|----------------------------|
| Pharmacies | 991 | 38 | 73 |

Figures above relate to inspection activity between 1 October 2017 and 31 December 2017.

The number of routine inspections over the period decreased from 1,021 to 991. The average number of inspections completed decreased from an average of 340 in Q2 to 330 in Q3 due to fewer inspections taking place in December. This is largely as a result of increased annual leave during this seasonal period and the planned reduction in inspections the week before Christmas when pharmacies are traditionally at their busiest.

3.2 Pharmacy premises not inspected

| Months since previous inspection | | 2016/17 | | 2017/18 | | |
|----------------------------------|-----|---------|---------|---------|---------|---------|
| | | Q3 | Q4 | Q1 | Q2 | Q3 |
| 36-38 months | No. | 659 | 451 | 569 | 505 | 627 |
| | % | 13.50% | 10.30% | 14.95% | 14.46% | 19.50% |
| 39-41 months | No. | 1,201 | 669 | 441 | 558 | 510 |
| | % | 24.70% | 15.30% | 11.58% | 15.97% | 15.86% |
| 42-47 months | No. | 2,091 | 2,186 | 1,655 | 1,004 | 984 |
| | % | 43.00% | 49.90% | 43.47% | 28.74% | 30.60% |
| 48 months or more | No. | 913 | 1,072 | 1,142 | 1,426 | 1,095 |
| | % | 18.80% | 24.50% | 30.00% | 40.82% | 34.05% |
| Total | No. | 4,864 | 4,378 | 3,807 | 3,493 | 3,216 |
| | % | 100.00% | 100.00% | 100.00% | 100.00% | 100.00% |
| Of all registered pharmacies | No. | 14,381 | 14,403 | 14,399 | 14,404 | 14,417 |
| | % | 33.80% | 30.40% | 26.44% | 24.25% | 22.31% |

Figures correct as at 31st December 2017

3.3 Age profile of pharmacies not inspected for 48 months and over

| Months since previous inspection | | East | North | South | West | Total |
|----------------------------------|-----|--------|---------|--------|--------|--------|
| 48 – 50 Months | No. | 165 | 71 | 135 | 80 | 451 |
| | % | 37.1% | 34.1% | 49.3% | 47.6% | 41.2% |
| 51 – 53 Months | No. | 202 | 87 | 112 | 61 | 462 |
| | % | 45.4% | 41.8% | 40.9% | 36.3% | 42.2% |
| 54 – 59 Months | No. | 78 | 49 | 27 | 27 | 181 |
| | % | 17.5% | 23.6% | 9.9% | 16.1% | 16.5% |
| +60 Months | No. | 0 | 1 | 0 | 0 | 1 |
| | % | 0.0% | 0.5% | 0.0% | 0.00% | 0.00% |
| Total | No. | 445 | 208 | 274 | 168 | 1,095 |
| | % | 100.0% | 100.00% | 100.0% | 100.0% | 100.0% |

Figures correct as at 31st December 2017

The number of pharmacies not inspected for 36 months or more has decreased for the fourth quarter in succession from 3,493 to 3216. As forecast, with the exception of the annual dip in December, we have continued to complete in excess of 300 inspections per month and in excess of 900 inspections this quarter to keep on top of the flow of pharmacies through the age categories. At the cut-off point for this performance report, one pharmacy had entered the +60 months category, which has now been inspected.

With our overall productivity we expect to maintain a 54 month maximum. However, this will vary month-by-month due to previous historical spikes in particular geographical areas. In this quarter, the number of pharmacies not inspected for +54 months increased to 181. Each inspector continues to focus on the pharmacies in their particular area which have not been inspected for the longest period.

In addition, we continue to deploy our inspectors in a flexible way which enables us to focus resource in those areas where there are a higher number of pharmacies that had not yet been inspected under the current model. So, to balance the workload, we have used inspectors within regions to assist their colleagues in different

areas, notably to inspect pharmacies in Leeds and Darlington, and in some cases, we have moved inspectors from one region to another to address geographical variables where there are a higher number of pharmacies that had not been inspected.

3.4 Top 5 standards ranked as not met

| Standard no. | Description | | Q2 Rank |
|--------------|---|----|---------|
| 1.1 | The risks associated with providing pharmacy services are identified and managed | 28 | 1 |
| 4.3 | 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 | 27 | 4 |
| 4.2 | Pharmacy services are managed and delivered safely and effectively | 21 | 3 |
| 1.2 | The safety and quality of pharmacy services are regularly reviewed and monitored | 20 | 5 |
| 1.7 | Information is managed to protect the privacy, dignity and confidentiality of patients and the public who receive pharmacy services | 20 | 10 |

3.5 Top 5 standards ranked as good

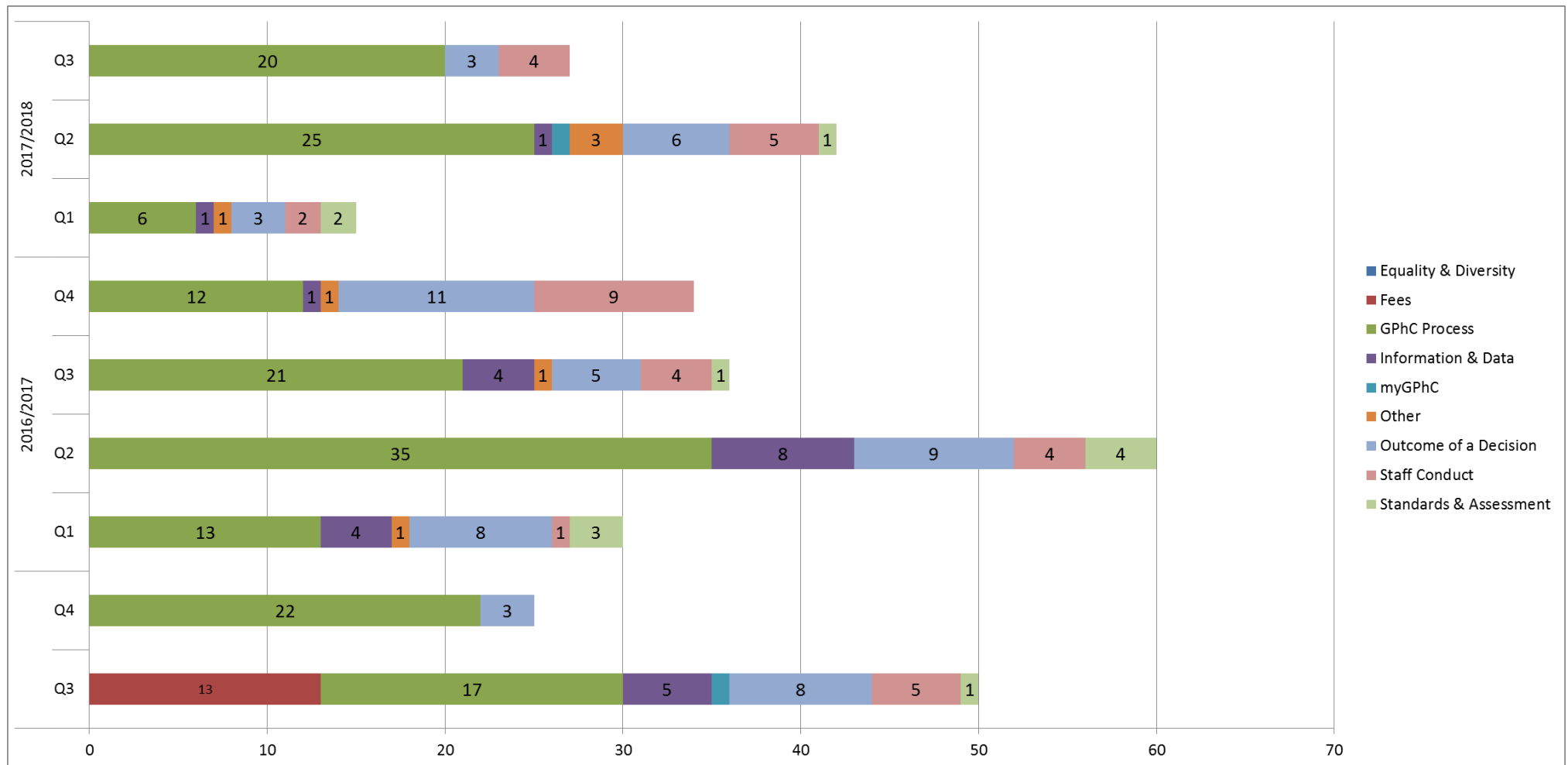
| Standard no. | Description | | Q1 Rank |
|--------------|---|-----|---------|
| 2.2 | Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training | 272 | 1 |
| 2.4 | There is a culture of openness, honesty and learning | 230 | 2 |
| 1.2 | The safety and quality of pharmacy services are regularly reviewed and monitored | 223 | 3 |
| 1.1 | The risks associated with providing pharmacy services are identified and managed | 183 | 4 |
| 2.5 | Staff are empowered to provide feedback and raise concerns about meeting these standards and other aspects of pharmacy services | 179 | 6 |

The above rankings relate to inspections carried out between 1 October 2017 and 31 December 2017.

The top five standards 'not met' have remained almost the same in this quarter with the exception of 1.7 entering the top 5 for the first time. It is too early to draw any conclusions on why the standard that relates to patient confidentiality has been elevated into the top 5 standards not met in this quarter but we will continue to monitor this to see if this is a continuing trend. Typically, the sorts of issues being found were prescriptions forms being left on the medicines counter and cases where the consultation room was being used for additional dispensing space but without appropriate precautions being taken to protect patient data. The top five 'good' standards have also remained the same apart from 2.5 swapping places with 4.2 (Pharmacy services are managed and delivered safely and effectively).

4. Complaints

4.1 Formal complaints and negative feedback by category



Figures correct as at 31st December 2017

4.1 Formal complaints and negative feedback by category (cont.)

Consistent with the trend highlighted in the last Performance Monitoring Report, there has been a continued year-on-year reduction in the overall number of complaints submitted to the GPhC. In addition, the pattern of complaint numbers in Q3 being less than Q2 has remained. This supports previous analysis which links the volume of complaints to the annual GPhC business cycle. As Q3 is outside our peak renewal period, the reduction in complaints is not unexpected.

20 of the 27 complaints received in this measuring period were about GPhC processes. No clear themes are apparent in the complaints. However, a small cohort (four) pertains to the applications process, while a further group of three complaints relate to a lack of or inaccurate information being provided. Three complaints were upheld: two on staff conduct, and one about the outcome of a decision. A further three complaints were partially upheld: two in relation to the registration assessment, and one about the applications process.

5. Education

5.1 Accreditation and recognition activity

| Course | Type | 2015-16 academic year | | 2016-17 academic year | | | | 2017-18 academic year |
|--|------------------------|-----------------------|----|-----------------------|----|----|----|-----------------------|
| | | Q1 | Q2 | Q3 | Q4 | Q1 | Q2 | Q3 |
| Master of Pharmacy (MPharm) degree | Accreditation | 2 | - | 1 | 4 | 4 | - | 1 |
| | Reaccreditation | 2 | - | - | - | - | - | - |
| | Interim visit | 0 | - | - | 5 | - | - | 1 |
| Overseas pharmacist assessment programme (OSPAP) | Reaccreditation | - | - | - | - | - | - | - |
| Independent prescribing | Accreditation | 2 | - | 1 | 1 | 1 | - | 1 |
| | Reaccreditation | 3 | - | 2 | 3 | 8 | 4 | 5 |
| | Monitoring visit | 1 | - | 2 | - | 1 | 3 | 0 |
| Level 3 Pharmacy technician knowledge/competence | Approval/Accreditation | - | - | - | - | - | - | - |
| | Reaccreditation | - | - | - | - | - | - | - |
| Level 2 medicines counter assistant and dispensing assistant | Accreditation | - | - | - | - | - | - | - |
| | Reaccreditation | 1 | - | - | - | - | - | - |

All events went ahead as scheduled.

A high volume of events are scheduled for the 2017-18 academic year, particularly for MPharm degrees and independent prescribing programmes. The bulk of MPharm events will take place in January – June 2018, and prescribing events will be taking place throughout the calendar year. The large number of events is due partly to natural peaks in the accreditation cycles but also to an increased interest in provision of 5-year integrated MPharm degrees. The increasing need for pharmacist prescribers has also led to increased funding for pharmacist prescribing programme places with consequent interest from new course providers. There are now 45 accredited independent prescribing programmes.

6. Human Resources

6.1 Headcount Overview

| GPhC | 31 st December 2017 |
|--|--------------------------------|
| Headcount | 233 |
| Permanent | 220 |
| Fixed Term Contract | 13 |
| Total Leavers | 10 |
| Permanent leavers | 10 |
| Turnover – Permanent (Oct-Dec) | 18.2% |
| Turnover – Permanent (Year to Date) | 14.9% |
| Stability – Permanent staff | 88.8% |

The data above summarises the headcount position during the period of 01/10/17 – 31/12/17. The total number of leavers for this period was 10 permanent employees. The turnover rate for permanent staff excludes those employees who were/are on a fixed term contract.

The total number of permanent leavers for this specific period equates to a turnover rate of 18.2%, however the year to date turnover rate is currently 14.9% due to fewer leavers in 2017 than 2016. The year to date 2017 figure is favourable when compared to the overall turnover rate of 20.9% for the whole of 2016.

The stability rate has been calculated based upon the number of permanent employees with more than 12 months employment at GPhC. On the 31st December 2017, there were **180** permanent employees who had more than a 12 month employment at GPhC. The stability percentage has increased from the previous reporting figure of 76.5%.

6.2 Organisational Absence – Absence Percentages

| Directorate | <u>Absence %</u> Oct 17 – Dec 17 |
|---------------------|-------------------------------------|
| Organisation | 2.8% |
| Executive Office | 1.90% |
| FTP | 0.92% |
| OD / EDI | 1.54% |
| Operations | 2.99% |
| Strategy | 2.84% |

The table above details the absence percentages for the organisation and the individual Directorates at GPhC. In total 298 working days were lost due to absence in this period. The overall absence percentage has not markedly changed, but we are reporting an increase from 2.0% to 2.8%. The Operations Directorate represents the highest absence percentage. Weekly confirmation to line managers has now begun to strengthen sickness notification processes. This involves a 'positive return' process whereby managers are tasked with confirming attendance of their teams regardless of whether they report any absence or not.

| Benchmarking | <u>Absence %</u> |
|---------------------------|------------------|
| GPhC in 2016 | 2.0% |
| CIPD - All Organisations | 3.3% |
| CIPD - Central Government | 4.8% |
| CIPD - Local Government | 4.6% |
| CIPD - Health | 4.8% |

Data taken from the CIPD Annual Survey Report 2016

6.3 Employee Relations

The table below is a summary of the Employee Relation cases by case type which were closed during the specified period:

| Case Type | <u>No. of cases</u> |
|--------------------|---------------------|
| Total Cases | 4 |
| Absence | 0 |
| Grievance | 1 |
| Performance | 2 |
| Other | 1 |

6.4 Learning & Development

In Q3, the L&D and HR team worked closely to ensure a smooth delivery of five distinct programmes. November saw the conclusion of the Bitesize Management Training-Recruitment and EDI which provided guidelines and support for hiring managers, including being mindful of equality and diversity during each stage of the recruitment process.

Between October and December 2017, 29 members of staff completed the eLearning Headtorch, which focusses on raising awareness around mental health in the workplace. This aimed to build resilience to stress as well as reduce the stigma of mental health in the workplace. We also delivered an in-house Train the Trainer workshop which aimed to build skills and confidence in designing and developing effective and meaningful training sessions. This will strengthen capacity and capability of in-house learning delivery. Both programmes received excellent feedback and we will be offering more employees the opportunity to sign up to both Headtorch and Train the Trainer this year.

Following a very successful Project Planning – Module 1, which yielded increased understanding of project management methodologies and practices and was rolled out in the first part of 2017, L&D supported the second module of Project Planning training, delivered in house by our Project Management SME. Benefits realised included increased use of best practice approaches to programmatic delivery which will enhance productivity and quality of outcomes. The programme received really good feedback and includes an in-house mentoring program on the topic.

Compliance training on Information Governance, created by the Governance team in partnership with L&D, was rolled out very successfully in October 2017 and reached 95% completion by the end of December.

A fully booked Unconscious Bias Training will be delivered in January and February and will help the GPhC members of staff to develop self-awareness about how background and experiences may impact decisions we are asked to make at work. Productivity gains associated with an unconscious bias-trained workforce include more effective management of compliance and ever-closer alignment with our organisational values to improve outcome delivery, e.g. improved resourcing decisions and the enablement of more robust decisions. The L&D team will also support the Program for Advanced Professional Certificate in Investigative Practice for the Fitness to Practice Team and a tailored Communication skills training for the Customer Service team.

| Table showing feedback on the question: “Will the training be helpful in your work?” | Strongly agree | Agree | Not Applicable | Disagree | Strongly disagree |
|--|----------------|--------|----------------|----------|-------------------|
| Headtorch | 52.94% | 41.18% | 0.00% | 5.88% | 0.00% |
| Recruitment and EDI (Bitesize) | 50.00% | 50.00% | 0.00% | 0.00% | 0.00% |
| Project Planning | 15.38% | 76.92% | 0.00% | 7.69% | 0.00% |
| Train the Trainer - Day 1 | 33.33% | 66.67% | 0.00% | 0.00% | 0.00% |
| Train the Trainer Day 2 | 80.00% | 20.00% | 0.00% | 0.00% | 0.00% |

Information Governance training – Mandatory training

Completion rate as of December 2017*: **95%**

*Rate provided by Governance team based on results from Smartsurvey knowledge tests completion

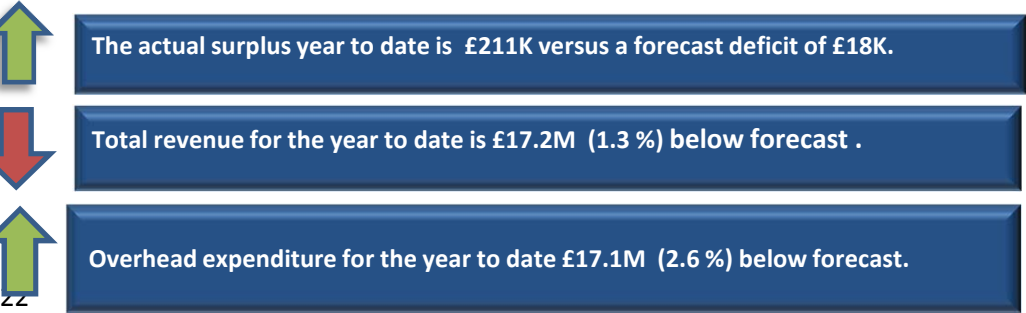
High level course description: Awareness training which aims to cover data protection, freedom of information, data quality, records management and various aspects of information security. Dates: Training was rolled out on 25th October.

Trainers: Information Governance SME training recorded on videos

Management Accounts

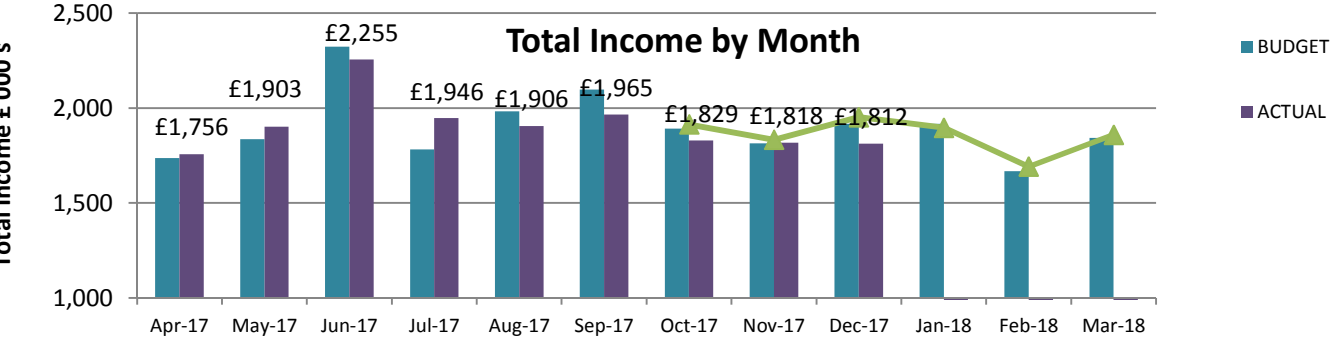
Summary of the Total GPHC organisation to 31 December 2017.

The year to date position for the organisation overall is a positive variance of £229K against the forecast including interest and tax .



Income

Registrant Income overall for the period is 1.5% below forecast expectation, with registrant numbers being marginally lower than forecast in all registrant groups.



Overheads

Employee costs: Payroll are £80K under spent overall for the year to date. The vast majority of this variance £70K is basic salary and associated payroll costs, due to a higher number of vacant roles than forecast. The remainder of the variance is attributed to a rebate received on employee health insurance.

Employee costs: Other are £100K below forecast, contractors are marginally under forecast due to a lower number of working days during the Christmas period. Recruitment and Training are also under forecast by £53K and £28K. Some of this variance is due to recruitment and training being delayed until the next quarter.

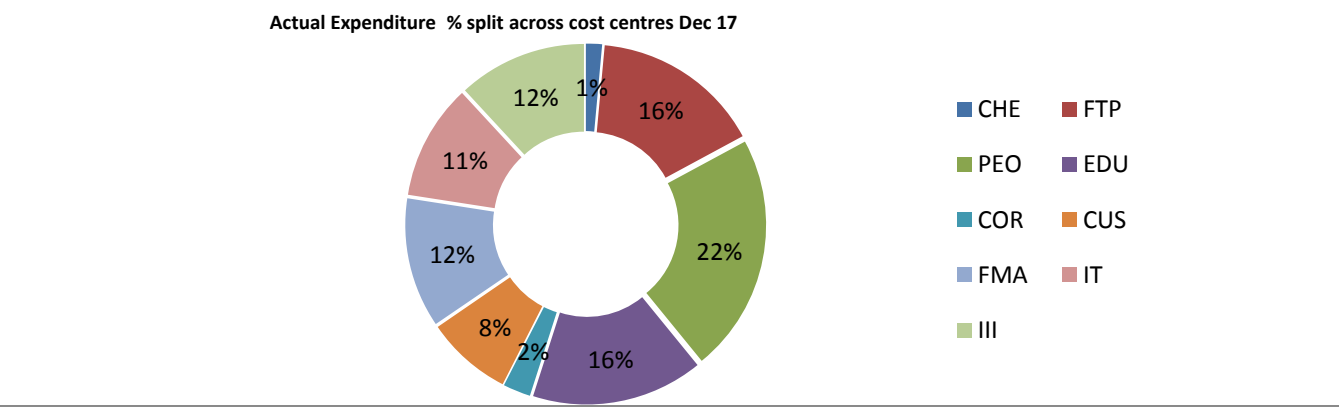
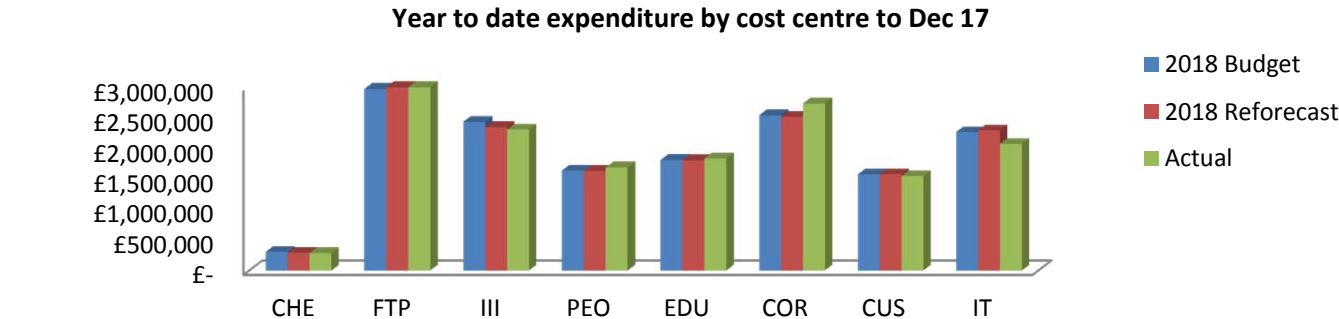
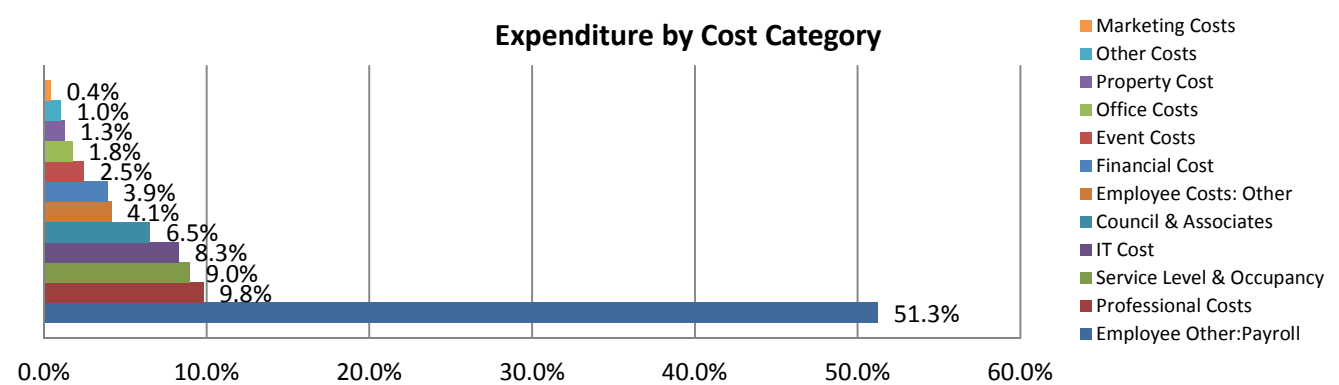
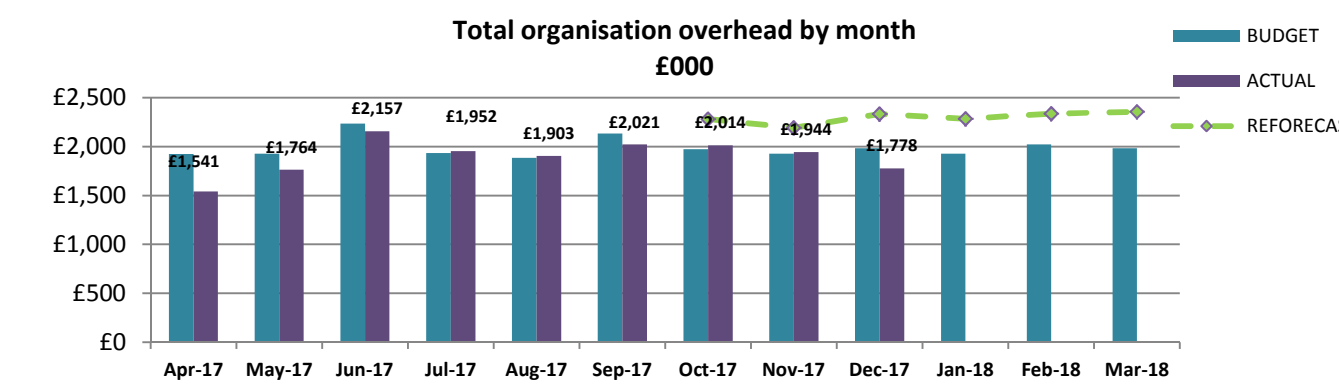
Council and associates cost are £43K under forecast expectations for the year to date. The cost of cancelled hearings is £95K. Attendance fee are £51K (5.7%) below forecast as the number of hearing days in December were lower than anticipated. Travel and accommodation costs overall were £21K underspent against forecast due to less panel members staying overnight and the average travel cost is lower.

Property costs are underspent for the year to date by £50K, mainly due to planned maintenance and repairs being postponed until the next financial year.

IT Costs overall are £119K under forecast mainly due to timing variances on development projects £80K and Technical Support £31K.

Professional Costs are under forecast by £151K. Consultancy costs are £66K behind forecast partly due to timings on projects, £40K is due to two pieces of consultancy being much lower than forecast . Professional fees are £31K underspent due to the reduction in the number of legal and clinical advisors required.

Research Cost the year to date forecast includes £30K for research on Initial Education and Standards which has been commissioned and is due to conclude in February 2018.



| STATEMENT OF FINANCIAL POSITION AS AT 31 DEC 17 | | |
|---|-------------------|-------------------|
| | 31-Dec-17 £000 | 31-Mar-17 £000 |
| Fixed assets | | |
| Tangible assets | 3,974 | 4,273 |
| Current Assets | | |
| Debtors | 1,330 | 1,646 |
| Bank and Cash | 31,166 | 26,963 |
| | 32,497 | 28,609 |
| Creditors | | |
| Amounts failing due within one year | -19,573 | -15,856 |
| Net current assets | 12,924 | 12,754 |
| Total assets less current liabilities | 16,898 | 17,027 |
| Creditors | | |
| Amounts failing due after more than one year | -2,887 | -3,227 |
| Provision for liabilities | -175 | -175 |
| Total Net assets | 13,836 | 13,625 |
| Funds employed | | |
| Accumulated surplus | 13,625 | 13,359 |
| Surplus/(Deficit) in Year | 211 | 266 |
| Total funds employed | 13,836 | 13,625 |

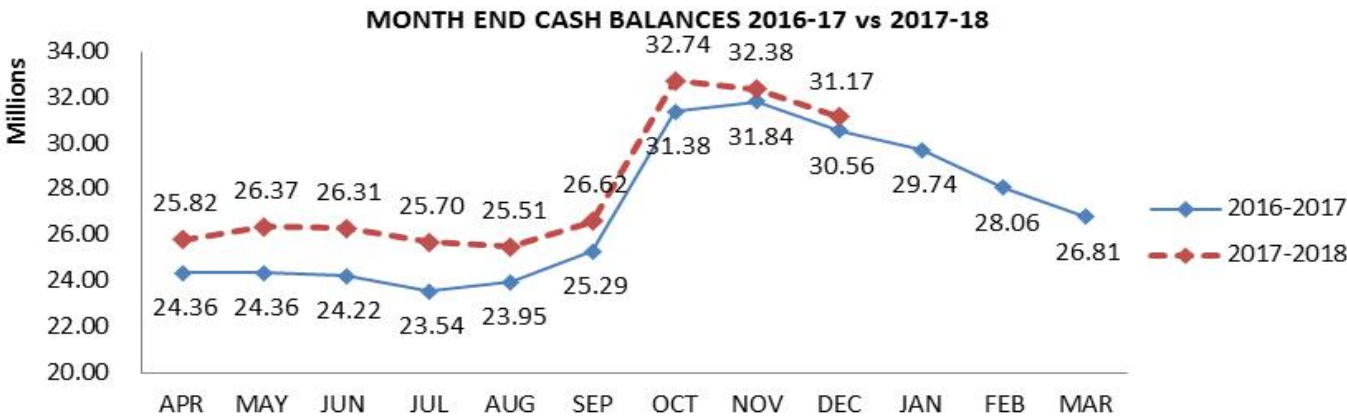
The balance sheet as at 31 Dec 17 shows a strong net position for the organisation.

Fixed Assets total £3.9M and relates to works carried out to the Canada Square office, office equipment purchased.

Current Assets of £32.5M includes cash held in bank accounts most of which relates primarily to registrants income. The debtors figures includes the cost recovery for high court appeals as well as prepayments. The high court debtors balance will be adjusted at the end of each financial year to include bad debt provision. Prepayments figures includes amounts paid in advance for rent, annual licences and subscriptions.

Current Liabilities include deferred income in relation to fees paid in advance for all registrant groups. October has the highest deferred income balance. Grant income relates to the building and will be released over the remaining term of the lease.

Long term Liabilities include the Landlords contribution to the office fit out which has been offset by the provision for future rent increases.



The current year cash balance shows a decrease when compared to previous months. The cash balance is highest in October when the majority of renewal payments are received. The cash balance will usually continue to decline until we reach the next peak renewal period

| BANK NAME | INVESTED FUNDS % | BALANCE | MATURITY DATE | RATE |
|------------------|------------------|-------------------|-----------------|----------|
| Goldman Sachs | 16% | 5,083,648 | Instant Access | Variable |
| Natwest Business | 4% | 1,156,270 | Over Night Swep | Variable |
| Nationwide | 16% | 5,000,000 | 10/09/2018 | 0.75% |
| Handelsbanken | 16% | 5,002,081 | Instant Access | 0.56% |
| Santander | 16% | 5,000,000 | Rolling | 1.15% |
| Lloyds Deposit | 16% | 5,000,000 | 06/06/2018 | 0.80% |
| Barclays | 16% | 5,000,000 | 29/05/2018 | 0.50% |
| Current Account | | 24,520 | Instant Access | N/A |
| | | 31,266,519 | | |

The table details how reserve funds are currently being invested, including the current account balance. During the current year the Lloyds and Nationwide funds, have been invested over 12 months instead of 6 months to achieve a better rate of return. A new NatWest overnight sweep account was opened during the quarter. This replaces the daily manual balance transfers from the Goldman Sachs reserve to maintain the £25K current

Annual plan progress report 2017/18













Quarter 3: October – December 2017

Introduction








This report provides an update on the key programmes of work in our Annual Plan 2017/18, which forms part of our Business Plan 2017-2020.




This reporting period covers quarter three - October to December 2017.

Overview

| Programmes of work | Status | Direction of travel |
|--|---|---|
| Developing our approach to regulating registered pharmacies to provide assurance and encourage improvement |  |  |
| Promoting professionalism through the standards for pharmacy professionals and related guidance |  |  |
| Providing further assurance to the public that pharmacy professionals are meeting the standards |  |  |
| Setting the standards and quality assuring the initial education and training for pharmacists and pharmacy technicians |  |  |
| Developing our data and insight strategy |  |  |
| Transforming our services and the way we work |  |  |

Key

| Status/direction of travel | Definition |
|---|--|
|  | Significant issues, aims may not be met to time/budget |
|  | Some issues emerging, aims still achievable |
|  | On track/completed |
|  | Not started |
|  | Rating Improved from last period |
|  | Rating worsened from last period |
|  | Rating from last period unchanged |

| | | | | | | |
|--|--|---|-----|---------------------|---|---|
| Developing our approach to regulating registered pharmacies to provide assurance and encourage improvement | | <table><tr><td>RAG</td><td>Direction of travel</td></tr><tr><td>A</td><td></td></tr></table> | RAG | Direction of travel | A |  |
| RAG | Direction of travel | | | | | |
| A |  | | | | | |
| Strategic aim: Registered pharmacies deliver safe, effective care and services | | | | | | |
| In 2017/18 we said we will: <ul style="list-style-type: none">develop and consult on detailed rules once parliamentary legislation has been approved and our powers are commencedpublish and consult on updates to our regulatory model for registered pharmacies including:<ul style="list-style-type: none">the introduction of further improvements to our inspection modelour proposals for publication of reportsdeveloping further our intelligence work streamimplement the statutory framework (enforcement powers) dependent on Rules timelinescarry out a consultation on new guidance for owners covering unregistered staff working in registered pharmacies, including pharmacy staff and managers | How we will measure success <ul style="list-style-type: none">Refer to covering paper | | | | | |
| Key links and assumptions <ul style="list-style-type: none">Publishing inspection reports requires a Commencement Order to be laid before Parliament.Registered Pharmacies Rules require Privy Council approval and statutory consultation | Main risks at presentRegistered pharmacies consultation: <ul style="list-style-type: none">The timescales for clearing draft Registered Pharmacies Rules and draft Commencement Order are dependent on Department of Health resources and prioritiesConsultation: How the pharmacy profession and public will respond to the Registered Pharmacies Rules and proposed refinements to the inspection approach Consultation on guidance for owners on the pharmacy team: <ul style="list-style-type: none">There are some stakeholder and registrant concerns about additional burden and disproportionality.Some respondents have concerns if, as a result of the changes we have | | | | | |

| | |
|--|--|
| | <p>proposed, there is no GPhC quality assurance of training programmes for unregistered pharmacy staff.</p> <ul style="list-style-type: none"> • The final guidance and regulatory framework do not achieve their aims and are not appropriately implemented and embedded in practice. • GPhC work streams on guidance for pharmacy owners and any changes to the inspection decision framework are not aligned with unregistered staff course approval and provision. |
|--|--|

Outline timetable:

| April-June 2017 | July-September 2017 | October-December 2017 | January-March 2018 |
|--|--|--|---|
| <ul style="list-style-type: none"> • Presentation of proposed refinements to inspection approach delivered to Council (11 May) • Continued drafting of Registered Pharmacies Rules | <ul style="list-style-type: none"> • Consultation on new guidance for owners on ensuring a safe and effective pharmacy team opens (20 July) • Final stages of drafting for Registered Pharmacies Rules • Further presentation to Council on inspection approach (11 July) | <ul style="list-style-type: none"> • Consultation on new guidance for owners on ensuring a safe and effective pharmacy team closes (11 October) • Council considers consultation report and approves final guidance at meeting on 7 December • Council considers format and content of published inspection report • Initial drafting of consultation document for Registered Pharmacies Rules and inspection approach • Pre-engagement with key stakeholders on our proposals on registered pharmacies ahead of the launch of the consultation | <ul style="list-style-type: none"> • Launch of new guidance for pharmacy owners on ensuring a safe and effective pharmacy team (January) • Council agreement to launch of consultation on Registered Pharmacies Rules and inspection approach |

Green – progressing well or done; Amber – started but not completed; Red – behind schedule; Black – not started or due yet

Commentary:

Registered Pharmacies Rules/Commencement Order

The finalisation and laying of the Registered Pharmacy Rules has been delayed. Work on the Rules continues, however, we are able to report that DH has confirmed that they are able to progress the commencement order for the Pharmacy (Premises Standards, Information Obligations, etc.) Order (“PSIO Order”), which will amend the Pharmacy Order to remove the requirement for the GPhC’s Standards for Registered Pharmacies to be set in Rules and it will improve our enforcement mechanisms. Commencement of the PSIO Order will also enable the publication of inspection reports. DH are yet to confirm a timeframe for the drafting and laying of the commencement order.

Inspection approach

We are continuing to develop our approach to inspecting registered pharmacies so that we use our existing resources more flexibly to support our strategic aims of assurance and improvement. This includes how we will inspect newer service models and how we will use intelligence effectively in the interests of patient safety.



We are continuing to refine the format of the inspection report that we intend to publish for routine inspections once the necessary legal powers have been commenced with a view to testing this with patient groups and members of the profession. This was discussed with Council on 12 October. Engagement with three public/patient focus groups across England, Scotland and Wales was completed during November and December to obtain feedback on the style, format and content of the inspection report. The feedback is being written up and considered and refinements will be made as a result, after which we will deliver a further presentation to Council on our proposed approach.

Consultation on pharmacy team

The consultation on new guidance for pharmacy owners closed on 11 October. We received 837 written responses to the consultation and a further 78 responses to a short survey targeted at unregistered staff. Work is ongoing to analyse the responses. Council was provided with an update on the work to develop guidance for the pharmacy team in November 2017. The consultation feedback raised a number of challenges which need to be carefully considered and it is important we ensure we have taken steps to mitigate unforeseen risks or consequences of our proposals. We will present the analysis report of what we heard from the consultation to Council for approval by June 2018.

The RAG rating is amber (a) due to the reliance on the Department of Health and the consequent uncertainty about the timetable for the Commencement Order and clearing the rules; and (b) that more time is required to develop our response to the consultation on the pharmacy team.

| EDI objectives: | | |
|---|---|---|
| Objective | Actions | Review and date |
| Guidance must take into account the outcomes of consultation and engagement with diverse groups of registrants, the public and their representative organisations | Conduct an EIA for the plans developed to provide more flexibility in inspection arrangements | The refined approach to inspection continues to be discussed at Council. An analysis of the potential impact of the regulatory model will be prepared as the approach develops and to inform any engagement/discussion with the pharmacy sector |
| Inspection arrangements must be flexible and responsive in terms of equality and diversity | Carry out an analysis of potential impact of the regulatory model for registered pharmacies at an early stage | As above |
| Our inspection reports must be easily accessible and published in a variety of formats | Explore EDI considerations for inspection reports, including accessibility for different audiences and managing requests for reports in alternative formats | Three patient/public focus groups are being held in Q3 to obtain feedback on the style, format and content of published inspection reports. This will inform our overall EDI considerations |

| Promoting professionalism through the standards for pharmacy professionals and related guidance | | RAG | Direction of travel |
|--|---|---|---|
| Strategic aim: The pharmacy team have the necessary knowledge, attitudes and behaviours | |  |  |
| In 2017/18 we will: <ul style="list-style-type: none"> launch our new standards for pharmacy professionals and support registrants to embed the standards in their practice through a comprehensive programme of communications and engagement agree, following consultation, new guidance on religion, personal values and beliefs develop and consult on draft guidance on raising concerns and whistleblowing | How we will measure success <ul style="list-style-type: none"> Refer to covering paper | | |
| Key links and assumptions <ul style="list-style-type: none"> The outcome of the additional consultation on religion, personal values and beliefs will have a significant impact on the launch of the new standards | Main risks <ul style="list-style-type: none"> The standards and guidance do not reflect Council's commitment to promoting a culture of professionalism and the delivery of compassionate person-centred care The standards and guidance do not reflect the relevant legal framework The standards are not sufficiently embedded in practice | | |

Outline timetable:

| April-June 2017 | July-September 2017 | October-December 2017 | January-March 2018 |
|--|---|--|--|
| <ul style="list-style-type: none"> Carry out pre-engagement on the new standards in April Report analysis of the consultation on religion, personal values and beliefs to Council in April (the standard) and June (the guidance) Launch new standards for pharmacy professionals in May 2017 Launch updated suite of supporting | <ul style="list-style-type: none"> Continue to support registrants to embed the standards in their practice through a comprehensive programme of communications and engagement | <ul style="list-style-type: none"> Scope options for how we review our raising concerns guidance Pilot of social media campaign to raise awareness of standards with patients and the public | <ul style="list-style-type: none"> Launch any new materials on raising concerns and whistle-blowing Further activities to raise awareness of standards among patients and the public, and students and trainees Development of Regulate articles with other organisations |

| | | | |
|---|--|--|--|
| guidance in May • Launch new guidance on religion, personal values and beliefs in June | | | |
|---|--|--|--|

Green – progressing well or done; Amber – started but not completed; Red – behind schedule; Black – not started or due yet

Commentary:

Having launched the new standards for pharmacy professionals and published guidance on religion, personal values and beliefs, we continue to focus on raising awareness of the new standards.

We are continuing to embed our new standards for pharmacy professionals in collaboration with the communications team. As our work on revalidation progresses and we begin to communicate with pharmacy professionals about revalidation, this will provide a mechanism for raising awareness of the standards with pharmacy professionals.

We will be piloting a social media campaign that aims to raise awareness of the standards with patients and the public. In October 2017 we partnered with the LGBT foundation to highlight how pharmacy professionals can demonstrate person-centered professionalism in a variety of situations. We have further articles planned with other organisations.



Our work to scope options for reviewing the raising concerns guidance remains on track, and we anticipate a staged approach to introducing new materials on raising concerns and whistleblowing over the course of 2018/19.

The above is reflected in additional activities which have been added to the initial timetable (these are underlined).

EDI objectives:

| Objective | Actions | Review and date |
|---|--|--|
| Standards for pharmacy professionals must be easily accessible using a variety of formats | Review and update the existing equality impact assessment (EIA) associated with the standards and ensure the accessibility of the standards and supporting resources | Produced supporting resources (standards wheel, poster, flyer, video and presentation) which are on the website and an app to improve access to the Standards for Pharmacy Professionals and the associated guidance. Completed. |
| | Produce an EIA summary and continually update it | The EIA on religion, personal values and beliefs covered |

| | | |
|--|--|---|
| | | the second consultation on the standards for pharmacy professionals and was presented to Council in June 2017. Completed. |
| Guidance supporting the standards for pharmacy professionals must benefit from consultation and engagement with diverse groups, registrants, the public and their representative organisations and take into account their responses | Conduct an EIA and resulting action plan for the guidance on religion, personal beliefs and the guidance on raising concerns and whistleblowing and update at all stages of implementation | Carried out a full EIA on the consultation on religion, personal values and beliefs which was presented to Council in June 2017. Completed. |

| Providing further assurance to the public that pharmacy professionals are meeting the standards | | RAG | Direction of travel |
|--|--|--|---|
| Strategic aim: The pharmacy team have the necessary knowledge, attitudes and behaviours | |  |  |
| In 2017/18 we said we will: <ul style="list-style-type: none"> consult on proposals which will further assure the public that pharmacy professionals are meeting the standards, following these steps: <ul style="list-style-type: none"> the draft consultation document is approved by our council the consultation takes place we analyse and report on the outcomes of the consultation the council reviews the responses to the consultation the council agrees the revised approach to the continuing professional development framework (subject to the consultation response) prepare for the implementation of the revised arrangements working with pharmacy representative groups develop a detailed communications and engagement plan to promote understanding and support involvement and compliance with the new model promote the learning and evidence we have received from the pilot and evaluation studies with other regulatory bodies | | How we will measure success <ul style="list-style-type: none"> The aims of our revalidation framework were set out as part of our consultation at the start of this financial year. Specific success measures are set out as part of the revalidation project and formed part of Council's decision on the framework in December. | |
| Key links and assumptions <ul style="list-style-type: none"> MyGPhC portal is a dependency. The revalidation business and technical change project is tracked separately via 'Transforming our services and the way we work'. | | Main risks at present <ul style="list-style-type: none"> At this phase in the development programme, particular work is taking place to mitigate risks related to lack of understanding or opposition to the proposed framework, or parts of it. MyGPhC portal does not function as desired | |

Outline timetable:


| April-June 2017 | July-September 2017 | October-December 2017 | January-March 2018 |
|---|--|--|--|
| <ul style="list-style-type: none"> Three month consultation with significant engagement activities and developing of approach to consultation analysis | <ul style="list-style-type: none"> Gathering and analysis of consultation responses Draft consultation analysis report for Council Reviewing the framework to take into account feedback from the consultation Review and update the Equality Impact Assessment (EIA) developed in previous phases of testing, piloting and evaluation using information drawn from the consultation and engagement events | <ul style="list-style-type: none"> Present consultation analysis report to Council (September meeting) Revalidation framework presented to Council for approval along with EIA Further implementation planning including communications work; guidance materials prepared Further development work to be informed by further meetings of the assurance and advisory groups | <ul style="list-style-type: none"> Operational implementation work Ongoing stakeholder engagement and development of support materials |

Green – progressing well or done; Amber – started but not completed; Red – behind schedule; Black – not started or due yet

Commentary:

- The Council reviewed the framework for implementation at its meeting in December 2017 subject to amendments that arose from what was heard in consultation.
- Work is taking place now to prepare for implementation by producing supporting materials. This work is also tied to the technical development of the new online portal for both renewal of registration and recording and submission of revalidation records.
- Engagement activities are continuing with a programme of speaking slots as well as the routine meetings of the revalidation advisory group.
- Work planning for next year is taking into account both implementation and also the development of a short and longer term evaluation strategy.

| EDI objectives: | | |
|---|--|---|
| Objective | Actions | Review and date |
| The framework must reflect the diverse needs of pharmacy professionals | Review and update the EIA developed in previous phases of testing, piloting and evaluation, using information drawn from the consultation and engagement with people and organisations affected by the proposals | <p>Consultation analysis is now complete and was submitted to Council in October 2017 (delayed by one month).</p> <p>The updated and finalised EIA will be submitted to Council in December and published on our website. Some areas for continuous monitoring have been identified to ensure proposals, over time, do not have negative impacts.</p> |
| The framework must reflect the needs of the countries of Great Britain by being adaptable to the different practice settings in those countries | | |
| An inclusive approach to engagement and consultation in the policy development phases | | |

| Setting the standards and quality assuring the initial education and training for pharmacists and pharmacy technicians | | RAG | Direction of travel |
|---|--|---|---|
| Strategic aim: The pharmacy team have the necessary knowledge, attitudes and behaviours | | A |  |
| In 2017/18 we said we will: <ul style="list-style-type: none"> publish new standards for the initial education and training of pharmacy technicians carry out further engagement with the sector and begin a formal consultation on new standards for the initial education and training of pharmacists review and consult on changes to the education standards for pharmacist independent prescribers working with others, establish a new work stream looking at our role in relation to the quality assurance of pharmacist and pharmacy technician pre-registration training in Great Britain. We are planning to: <ul style="list-style-type: none"> analyse research on key issues across pre-registration pharmacy training engage with funders, commissioners and providers of education and training publish a discussion paper and draft proposals begin our review of the accreditation methodology for both pharmacist and pharmacy technician initial education and training, including: <ul style="list-style-type: none"> carrying out an evaluation of our MPharm interim events carrying out research and analysis of distance-based learning for pharmacy technicians engaging with national awarding bodies, pharmacy schools and FE Colleges | | How we will measure success <ul style="list-style-type: none"> Refer to covering paper | |
| Key links and assumptions <ul style="list-style-type: none"> For the review of initial education and training of pharmacists, there are potential links to government reforms to the structure and funding of education across Great Britain. There are also links for independent prescribing accreditation to the additional funding for national commissioners of education and public policy priority in this | | Main risks at present <ul style="list-style-type: none"> There is a risk that some awarding bodies or course providers are unaware of the level of change required to successfully implement the new IET PT standards. To mitigate against this risk we are producing an operational guidance document (the evidence framework) while actively engaging with awarding bodies and course providers to maintain an up-to-date | |

| | |
|-------|---|
| area. | <p>understanding of the implications of the new standards.</p> <ul style="list-style-type: none"> • We are currently in the scoping phase of the Q/A review work stream. We have begun internal planning work and will be presenting a high level scoping plan in the autumn, informed by Council's workshop deliberations in November. We will need to agree an overall strategy and timescale for delivery which will have an impact on resources and is a potential risk for the team going forward in delivering this work stream. • We have changed our approach to developing new initial education and training standards for pharmacists, specifically rather than starting to draft new standards in 2017. We have invested time and effort in engaging with in excess of 50 key stakeholders. This has generated a rich base of information to inform our standards development work, which will now begin in 2018. |
|-------|---|

Outline timetable:

| April-June 2017 | July-September 2017 | October-December 2017 | January-March 2018 |
|--|--|---|--|
| <ul style="list-style-type: none"> • IET Pharmacy Technician (PT) standards consultation analysis report presented to Council and next steps agreed • Agreed new education governance framework and programme/project methodology • Reviewed and updated the PT IET standards | <ul style="list-style-type: none"> • Progress report on work programme sent to Council to note • Implemented new governance framework for management of the work programme • Engaged with key stakeholders to ensure the IET PT standards are fit for purpose and achievable • Develop a draft education framework document to provide additional information and clarity on the IET PT standards • Pre-consultation engagement meetings for IET Pharmacist standards and ET Pharmacist | <ul style="list-style-type: none"> • Continue engagement for IET Pharmacist standards and ET Pharmacist Independent Prescribing (PIP) Standards • Publish IET PT standards and draft evidence framework document • Implementation engagement phase with PT stakeholders • First Pharmacists Education Standards Advisory Group (EAG) meeting • Registration criteria & Supervision proposals for PTs presented to Council for approval | <ul style="list-style-type: none"> • Second EAG meeting scheduled • Launch Pharmacist Independent prescribing consultation (January) • Formal engagement events for ET PIP Standards (x3) |

| | | | |
|--|--|--|--|
| | <p>Independent Prescribing (PIP) Standards</p> <ul style="list-style-type: none"> • Draft IET PT standards presented to Council in September for approval • Council workshop on education, with a focus on QA and PT education and training with external expert input | <ul style="list-style-type: none"> • Q/A workshop with Council • Council approve the consultation document for ET PIP Standards review | |
|--|--|--|--|

Green – progressing well or done; Amber – started but not completed; Red – behind schedule; Black – not started or due yet

Commentary:

Initial education and training standards for pharmacy technicians: These standards are now agreed and in the implementation phase. What we have learnt is that facilitating a smooth transition to courses based on the new standards, which are quite different from the old ones, will be as challenging as actually developing them. With an expanded education policy team we have the capacity to implement a programme of engagement activities with course designers and providers, which we have begun. We are ready to engage with providers to accredit new courses at any time but the timing will be a matter for providers not us.

Education and training standards for pharmacist independent prescribers: We have moved presenting the consultation document to Council for consideration back by one meeting to early February 2018 (which is reflected as such with the red rating in the timetable). This is to allow further discussion with stakeholders about a number of issues arising from our extensive round of pre-consultation meetings with schools of pharmacy offering IP courses, other IP course providers and other stakeholders.

Quality in education: This work stream is in development. We have begun to shape it by engaging with Council in workshop mode. In addition we have sought input from our new external Education Advisory Group, which met for the first time in October. We plan to have a scoping discussion with the Senior Leadership Group between late February and early March. Following this we will test early proposals in a workshop with Council in April.

Initial education and training standards for pharmacists: We have begun this work stream with a comprehensive series of pre-consultation workshops, including meetings with every school of pharmacy, the RPS, BPSA, HEE/NES and pharmacist pre-registration training providers. These meetings are being written up and will be used to inform our drafting work in 2018.

The amber rating reflects the fact that although new governance arrangements have been agreed under a new sponsor, they have only just been implemented, so will need time to embed. This is a complex programme with upcoming critical milestones, external risks and considerations to actively manage.

| EDI objectives: | | |
|--|---|--|
| Objective | Actions | Review and date |
| Standards for initial education and training of pharmacy professionals must benefit from consultation and engagement with diverse groups, registrants, the public and their representative organisations and take into account their responses | Provide evidence of early EDI considerations in development of the consultation | When developing the new standards, which are now in force, a separate standard on EDI was included |
| | Develop an EIA for standards | When the draft and final standards were sent to Council they were accompanied by an EIA, which was revised after the consultation to reflect the reviews we received |
| | Complete a summary EIA for circulation and updates | We will complete a summary EIA as part of the implementation phase for the standards. |

| Developing our data and insight strategy | | RAG | Direction of travel |
|---|---|-----|---------------------|
| Strategic aims: The pharmacy team have the necessary knowledge, attitudes and behaviours Registered pharmacies deliver safe, effective care and services Pharmacy regulation is efficient and effective | | A | ↑ |
| In 2017/18: <ul style="list-style-type: none"> We have presented to Audit and Risk Committee our approach to reviewing the scope and developing a forward plan for this work. Audit and Risk Committee has agreed the approach and we expect to come to Council for approval of the forward plan by July 2018. | How we will measure success | | |
| Key links and assumptions <ul style="list-style-type: none"> Requirements from the business on the reporting, analysis and insight are needed before we can identify the data needed to develop a new data model for the Data Warehouse. External dependencies on the registered pharmacies work programme to inform development of published insight reports into key themes within pharmacy. | Main risks at present <ul style="list-style-type: none"> The development of the insights and intelligence strategy is the key building block to inform the scope, sequencing and resource requirements of all further follow on work programmes, including the design and build of the data warehouse. Capacity and capability of the data and insights team to deliver the work programme | | |

Outline timetable:

| April-June 2017 | July-September 2017 | October-December 2017 | January-March 2018 |
|--|---|---|--|
| <ul style="list-style-type: none"> FtP Case Tracker – change data integration to ensure continued operational and organisational reporting is maintained in moving from FtP to CRM database Data sharing - Co-designed approach to sharing data with NHS Education | <ul style="list-style-type: none"> FtP Case Tracker – <ul style="list-style-type: none"> Deliver continued reporting post go-live Begin to increase use of CRM dashboards for FtP to improve access to performance and management information | <ul style="list-style-type: none"> FtP Case Tracker – Post go-live – Requirements gathering to define new dashboards for reporting Organisational restructure creating a new directorate of Insights, Intelligence and Inspection. Putting in place senior executive | <ul style="list-style-type: none"> Commence programme of work to inform the development of the Insights and Intelligence Strategy. To include: <ul style="list-style-type: none"> The gathering of business requirements of current and future data and insight needs |

| | | | |
|---|---|--|--|
| <p>For Scotland</p> <ul style="list-style-type: none"> Analysing online workshops looking at factors affecting quality in pharmacy MI & KPI audit - Reported to SLG on the proposed management responses to the recommendations and developing a cross-directorate data project which covers effectively the key areas identified in the report | <ul style="list-style-type: none"> Begin to phase out Tableau outside the D&I team Data project – Workshop with Council on capturing requirements for new Council Business reporting Report on initial research on factors affecting quality in pharmacy Evaluation on consultation process best practice | <p>level leadership for the insights and intelligence agenda</p> | <p>at operational and strategic level</p> <ul style="list-style-type: none"> And engagement with key stakeholders Commission qualitative analysis of inspection reports to identify insights |
|---|---|--|--|

Green – progressing well or done; Amber – started but not completed; Red – behind schedule; Black – not started or due yet

Commentary:



- During this quarter the organisation has successfully restructured, creating a new Insights, Intelligence and Inspection directorate to reflect the strategic focus of the organisation over the next few years, and specifically in relation to our data, insights and intelligence work.
- A new director is now in place to provide executive level leadership and oversight in this important area of work.
- In light of the above, the work programme for the remainder of the year has been reviewed and reprioritised for the last quarter to focus on gathering business requirements on current and future data needs at an operational and strategic level. This is necessary to inform the development of an insights and intelligence strategy and to inform the design of the new data warehouse.

An update on each objective for achievements to date and planned next steps:

- A programme of focus groups and one to one meetings is planned for February to April to gather the organisation's current and future operational and strategic data needs to inform the development of the Insights and Intelligence Strategy. This will include some meetings with stakeholders such as those we have memorandums of understanding with for information sharing.
- We are liaising with the different parts of the business to adopt standardised EDI categories within their data capture processes and systems as appropriate
- We are continuing our discussions with key stakeholders to develop our Information Sharing agreements to share data from our regulatory functions.
- The joint inter-regulatory insight group with the Health and Social Care Regulators Forum have agreed to meet. We have facilitated the reforming of the joint inter-regulatory research group which will meet in January 2018. We are also actively engaging with other regulators directly to share learning on insight.
- The initial research on factors affecting quality in pharmacy using crowd sourcing technology will be summarised in a paper for discussion.

- We are commissioning some exploratory machine learning analysis of inspection reports to understand how this technology may be able to help us gain insights from our reports on an ongoing basis. We are also commissioning some qualitative analysis of inspection reports to identify key themes within pharmacy to develop some insight reports.

| EDI objectives: | | |
|---|--|---|
| Objective | Actions | Review and date |
| Our work must benefit from and must take into account baseline EDI data | Continue the roll out of a standardised approach to collecting data on protected characteristics | We are liaising with the different parts of the business to adopt the agreed EDI categories within their data capture processes in line with existing project developments |
| | Develop a portal for a suite of GPhC EDI data accessible to staff | No further progress has been made on this action to date. Details on the business requirements to be captured are needed to clarify this action before we can begin any development |

| Transforming our services and the way we work | | RAG | Direction of travel |
|---|--|---|---|
| Strategic aim: Pharmacy regulation is efficient and effective | |  |  |
| In 2017/18 we will: <ul style="list-style-type: none"> • revise and update the IT strategy • implement the governance arrangements for the IT architecture delivery plan • implement the revised case tracker • implement the revised revalidation (CPD) portal • develop the wider service transformation plan | How we will measure success <ul style="list-style-type: none"> • External audience will find it increasingly easy and efficient to engage with us • Staff will feel more engaged and positive • We are seen to progress our key priorities effectively and efficiently • We can demonstrate the extent of savings or improved value | | |
| Key links and assumptions <ul style="list-style-type: none"> • The IT platform needs to be in place for revalidation and online registration to proceed • Effective senior decision making is needed to allow progress • Assumption that level of staff turnover doesn't increase | Main risks <ul style="list-style-type: none"> • Clarity of aims, expectations and scale of ambition for transformation • Effectiveness of senior decision making • Interdependencies between multiple pieces of work • Reactions to change will need to be managed • Cynicism/frustration at pace of change | | |

Outline timetable:

| April-June 2017 | July-September 2017 | October-December 2017 | January-March 2018 |
|--|---|--|--|
| Case tracker: approve requirements; IT development Revalidation portal: requirements gathering; IT development IT platform: select development partner; technical architecture development; create infrastructure requirements Transformation: appoint Deputy CEO to lead on transformation | Case tracker: system and user testing; training staff; go-live Revalidation portal: IT development; external user reviews IT platform: technical architecture development; infrastructure and operational services development and testing Transformation: establish aims and priorities for transformation; address | Case tracker: post go-live support and review Revalidation portal: IT development; external and internal user reviews IT platform: technical architecture development; infrastructure and operational services development and testing Transformation: embed culture reset; establish mechanisms to improve | Case tracker: implement system improvements Revalidation portal: final development and fixes for initial go-live; public launch IT platform: implementation as part of revalidation launch Transformation: measure and refine cultural impact work; strengthen risk processes; measures to reduce silo working; improve forward planning of |

| | | | |
|--|---|---|--|
| | SLG decision making; re-engage staff on transformation; initiate new paper to digital projects. | accountability for progress and conflict resolution; set clear priorities for next year with success measures; staff survey; develop on-line registration; review of website needs; develop HR/finance integration. | work; testing for on-line registration; prepare for tender for website development |
|--|---|---|--|

Green – progressing well or done; Amber – started but not completed; Red – behind schedule; Black – not started or due yet

Commentary:

Case tracker

What is the project designed to deliver for the GPhC? - A new IT system using CRM covering the 'as-is' end to end fitness to practise process and integrated with the GPhC's online concerns form to replace current case management systems.

Where are we now? - Case tracker went live on 5 September 2017. Post go-live system improvements and refinements were implemented in December 2017. This included work on management information dashboards and exception reports. Work is in progress for next deployment in February 2018.

What is to come? – Project closure by end of March 2018. Further work on fitness to practise reporting will be taken forward as part of data warehouse work.

Revalidation portal

What is the project designed to deliver for the GPhC? - The project is a component of a wider programme of work to introduce revalidation for pharmacy professionals. The objective of this project is the successful delivery of the new online revalidation system (as part of myGPhC) for public launch in Spring 2018 to allow registrants to record their revalidation entries ahead of the first renewal window, with remaining back office (audit) functionality and new revalidation requirements delivered by Autumn 2018.

Where are we now? - This project continues to progress well. All requirements for initial go-live have been developed and are ready for testing. A detailed communications plan has been developed to support the public launch.

What is to come? – User testing (both internal and external); preparation for go-live, including communications to registrants about new myGPhC. The second phase comprising back office (audit functionality), submission and review will follow on from this work.

IT platform for web services

What is the project designed to deliver for the GPhC? - As part of our IT strategy, this project will set up the IT cloud infrastructure (Azure) and technical architecture for online services. It is a critical dependency for the revalidation portal and registrant online services projects.

Where are we now? – Since last update, an Azure contract resource is now in post and the infrastructure work has progressed with the majority of requirements confirmed and end-to-end user test infrastructure created. The redevelopment of myGPhC (online renewals) was completed in November and testing completed in December 2017.

What is to come? – Create remaining Azure infrastructure environments. Test Azure infrastructure and online application (myGPhC), including functional testing, external review, accessibility review and penetration testing (capacity and security). Establish Azure operating procedures and processes. Prepare for initial go-live of Azure infrastructure and myGPhC application.

Registrant online services.

What is the project designed to deliver for the GPhC? - The objective of the project is deliver a range of online services for registrants, applicants and trainees (these are currently paper based) covering applications for registration (pharmacists and technicians), pre-registration, the registration assessment (exam), removal and restoration in phases during 2018/19.

Where are we now? – Project Initiation Documentation has been approved. Requirements gathering for the initial implementation of new online services (pre-registration, exam and pharmacist applications) has been completed. This included input from staff and external reviewers (registrants).

What is to come? – IT development to start in January using an agile approach then testing after which there will be an assessment of the most viable go-live date.

Transformation

What is transformation designed to deliver for GPhC? – To improve the way we work and to shift our processes from paper to digital so that we can focus our effort on more value added activities instead of manual processing.

Where are we now? – Paper to digital projects are progressing well. We are making strong progress on seeking to advance in several areas at once instead of sequentially. Cross-directorate collaboration is strong on these projects. In this period there has been a strong focus on SLG working effectively as a team, setting a refreshed strategic direction. The Performance and Delivery Board pilot continues towards a review in February. Business planning has progressed well, budgeting for the new business plan is behind schedule. We are starting to look to strengthen our risk processes, including aligning these more closely with our planning and budgeting work.

What is to come? – Completion of P&D Board pilot; focus on risk management; agree culture work forward plan; more detailed summary plans below the business plan.

Dependencies and interdependencies between these pieces of work continue to be monitored with input from members of all project teams. Equality Impact Assessments (EIAs) are standing items on project board meetings.

The RAG rating is amber although most elements of the work are ‘green’. That is due to the work to align the budget with the business plan and keeping the momentum on the culture work being behind schedule. HR/finance integration work is behind schedule due to resourcing constraints.

EDI objectives:

| Objective | Actions | Review and date |
|---|---|--|
| The service transformation project must make sure new services are accessible and meet the needs of everyone using them | Undertake an EIA of the revised IT strategy and the service transformation plan | EIA for case tracker was reviewed by the project board in October 2017 following go-live. EIA is a standing item on the project board agenda. EIA will be reviewed as part of project closure. EIA for the revalidation online system drafted and included as part of the revalidation for pharmacy professionals consultation. EIA is a standing item on |
| | Complete summary EIAs for circulation and updates | |

| | | |
|--|--|--|
| | | <p>the monthly board agenda and was reviewed by the EDI Development Manager at the December 2017 board meeting.</p> <p>EIA for registrant online services has been drafted as part of project initiation and will be reviewed by the board at January 2018 meeting.</p> <p>An independent accessibility review for new myGPhC has been scheduled in February 2018.</p> |
|--|--|--|



Meeting paper

Council on Thursday, 08 February 2018

Public business

Consulting on education & training standards for pharmacist independent prescribers

Purpose

To agree draft education and training standards for pharmacist independent prescribers for consultation and a mechanism for implementing the manner in which pharmacist independent prescribers in training are supervised.

Recommendations

Council is asked to agree:

- i. a consultation document for new education and training standards for pharmacist independent prescribers; and
- ii. a mechanism for allowing proposed changes to the educational supervision of pharmacist independent prescribers in training to be introduced in advance of the accreditation of courses based on new standards.

1. Introduction

1.1. In common with other healthcare roles, the pharmacist one is evolving rapidly. As new demands are placed on the healthcare systems in Great Britain, pharmacists are being used increasingly as clinical members of the front-line healthcare team. In that context, one way in which the practice of many pharmacists is developing is as independent prescribers. In this paper and accompanying documents, we are bringing forward proposals to modernise the education and training standards for pharmacist independent prescribers.

- 1.2. In order to become an independent prescriber, a pharmacist must pass a course at university comprising academic study and also practical experience of patient consultation, diagnosis and prescribing. The standards in this consultation document describe the prescribing knowledge, skills and attributes a pharmacist will acquire on successful completion of a course and also requirements for course providers.
- 1.3. The draft standards incorporate input from all schools of pharmacy delivering independent prescribing courses and other course providers, through over 40 pre-consultation engagement meetings, and feedback from a sense-checking workshop with a group of pharmacist independent prescribers and courses providers. This pre-consultation work took place between October 2017 and January 2018.
- 1.4. Appendix 1 is the draft consultation document,
- 1.5. Appendix 2 is an equality impact assessment supporting the consultation.
- 1.6. Section 2 below sets out the proposed changes in detail.

2. Key changes to the standards

2.1 We are proposing three key changes to the education and training of pharmacist independent prescribers:

- revising the pre-requisite entry requirements for training;
- introducing learning outcomes; and
- Revising educational supervision requirements for pharmacist independent prescribers in training: from designated medical practitioner to designated prescribing practitioner.

2.2 Proposal 1: *Revising the pre-requisite entry requirements for training*

2.2.1 Currently, course applicants must have worked in a patient-facing area¹ for two years before training to prescribe in that area and must have the relevant pharmacological knowledge and skills to support their prescribing training before they begin the course. We believe this places too much emphasis on the time requirement and not enough emphasis on relevant prior knowledge and skills. Also, we have no evidence to suggest that time alone spent in a particular area produces applicants of the right quality to train.

2.2.2 For these reasons, we propose that the two-year time pre-requisite should be removed, and replaced with an effective, but not burdensome, application process in which an applicant's experience is verified by course providers to ensure that they are ready to train. This does mean that the time required of applicants to demonstrate they have met course pre-requisite entry

¹ The current wording is 'in a UK hospital, community (pharmacy) or primary care'.

requirements will vary, depending on their experience and skills, and may be more or less than two years.

2.2.3 The kind of evidence that would be appropriate to demonstrate an applicant's suitability to train as a prescriber includes:

- i. patient-facing work experience;
- ii. involvement in clinical prescribing led by other prescribers;
- iii. participating in clinical interventions and medicines optimisation activities to improve patient outcomes; and
- iv. participating in multi-disciplinary aspects of prescribing.

2.2.4 The list above is indicative not exhaustive and could reasonably be presented by a pharmacist working with patients in any sector. The ultimate responsibility for checking that an applicant is suitable to train rests with the course provider, as it does now (and as it does for any course of education and training). However, to support consistency across course application processes we will provide guidance on illustrative types of appropriate pre-requisite evidence in a separate document, an evidence framework (see 1.6 Further Work in the consultation document).

2.2.5 From a practical perspective, if these activities have been captured in advance of an application to join a course in continuing professional development (CPD) entries or revalidation activity, they could be used as part of the application evidence base.

2.2.6 To address any concerns that removing the time requirement would lead to a reduction in the quality of pharmacist independent prescribers we are proposing an explicit additional provision in the standards that course providers should reject applicants who are not suitably experienced. Having considered the evidence, we have reached the conclusion that removing the time requirement will place the emphasis where it should belong: on the quality of prior knowledge and skills not solely the quantity of it.

2.3 Proposal 2: *Introducing learning outcomes*

2.3.1 We propose to introduce new learning outcomes for the pharmacist independent prescribing standards. Introducing learning outcomes brings these standards in to line with contemporary practice and our other standards, which emphasise outcomes – what people can do – rather than inputs.

2.3.2 The learning outcomes will describe the knowledge and skills a trainee should have achieved on successful completion of a course. We believe that they are sufficient to describe what a course

must cover, so we do not think it is necessary to produce a detailed syllabus as well. This approach is consistent with our approach to other new sets of education and training standards.

2.3.3 The learning outcomes are general, not specific, and the knowledge and skills in them can be applied in any prescribing area. This means that courses may choose to focus on relatively narrow, specialist area or broader ones, such as general practice or accident and emergency, or both. This reflects the reality of contemporary prescribing practice.

2.4 Proposal 3: *Revising educational supervision requirements for pharmacist independent prescribers in training: from designated medical practitioner to designated prescribing practitioner*

2.4.1 Currently, only doctors are allowed to supervise trainees formally as designated medical practitioners (DMPs). In reality, while DMPs sign off trainees, other healthcare professionals offer trainees support and advice, sometimes using their own expertise as prescribers.

2.4.2 We are proposing that in the future, pharmacists training to be independent prescribers could be supervised formally not only by DMPs, but also by experienced pharmacist prescribers and other experienced prescribers. We think it is important that trainees decide what kind of prescribing supervisor they have, in consultation with their course provider. For example, if a trainee thinks that being supervised by a doctor would be most helpful to them then they should be supervised by a doctor, but if they feel that a pharmacist would be more appropriate, that would now be an option.

2.4.3 This change would remove a potential barrier to the expansion of the number of pharmacist independent prescribers and alleviate pressure on both course providers and, ultimately, service providers. Giving this responsibility to practising pharmacist independent prescribers would also give them the opportunity to train the next generation and share their experience in the workplace.

2.4.4 In recognition of the change, we plan to alter the DMP title to DPP – Designated Prescribing Practitioner. While the title will change, the role will not: DPPs will sign off trainees as well as assessing their competence in accordance with the requirements of course providers and also giving trainees support and advice. In addition to having a DPP, trainees may continue to draw on the support and advice of other healthcare professionals, including other prescribers.

2.4.5 We will put in place some requirements for the supervisors to make sure they have the necessary skills and experience to be able to effectively supervise, assess the competence of and sign off a trainee (see 1.6 Further Work in the consultation document).

Implementing the DPP

- 2.4.6 We have reflected on this change and propose to decouple its introduction from the other standards, allowing it to be introduced in advance of new courses based on the full set of standards. The purpose of this is to allow existing courses to expand their pool of prescribing supervisors once the standards have been agreed and separate, revised guidance for them has been issued but without necessarily applying for a full course reaccreditation. Our reasoning is that if a course provider has been reaccredited recently, it would be unnecessarily burdensome to require them to resubmit again just to permit the introduction of designated prescribing practitioners.
- 2.4.7 As a safeguard, course providers wanting to introduce the designated prescribing practitioner role in advance of submitting their course for full reaccreditation will be subject to a paper-based, GPhC accreditation exercise focused on just that one change.

3. Equality and diversity implications

- 3.1 Equality and diversity implications are discussed in full in the equality impact assessment (EIA) accompanying this paper. To date we have not identified any implications but we have included several questions about equality and diversity in the consultation and will update the EIA as part of the consultation analysis.

4. Communications

- 4.1 These draft standards will be subject to a three-month consultation and we will be producing a communications plan for this activity.

5. Resource implications

- 5.1 This consultation has been budgeted for.

6. Risk implications

- 6.1 If the new standards are not introduced, the existing ones will age with time and risk becoming unfit for purpose. In turn this might mean that pharmacists training to become independent prescribers are also not fully fit for purpose.
- 6.2 If the changes to supervision are not made, the pool of supervisors will remain solely doctors and this may restrict the expected growth of independent prescribing courses and also the number of pharmacist independent prescribers.

7. Monitoring and review

7.1 Once the consultation has been completed, a public analysis will be produced and revised standards will be brought to Council for further consideration.

7.2 Once implemented, new standards will be reviewed fully again in another 5/6 years.

Damian Day, Head of Education

General Pharmaceutical Council

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22nd January 2018

Consultation on education and training standards for pharmacist independent prescribers

DRAFT

March 2018

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The deadline for responding to this consultation is 4T

Foreword

Pharmacist independent prescribers are already playing a vital role in delivering high quality care to people in the health services of Great Britain. Pharmacists have been able to train and practise as independent prescribers for over a decade now, but the demand for them has increased significantly over the last few years, and government policies and the changing demands from health services and patients across Great Britain suggests the need for well-trained pharmacist prescribers will continue to grow.

As demand for has increased, course providers have expanded their provision to keep up with demand. As the regulator, we have a responsibility to make sure that the education and training pharmacists must complete in order to become an independent prescriber is fit for purpose, equipping them with the necessary knowledge, attitudes and behaviours to successfully take on the role, providing safe and effective care to the people using their services.

Alongside an increase in the number of pharmacist independent prescribers, the prescribing role has developed significantly in recent years. When it began, pharmacist independent prescribing was based around quite narrow specialisms but what we have learnt from our own research is that pharmacists have broadened their role once qualified and many are now working as generalist prescribers in GP practices, emergency departments, online and in other settings. In many cases this is in direct response to government initiatives. In light of these changes, we are making improvements to the standards for training of pharmacist independent prescribers to make sure the learning outcomes in them are clearly focused on the current prescribing role and that courses are fit for purpose.

The standards for the education and training of pharmacist independent prescribers presented for consultation in this document are part of a suite of education and training standards for members of the pharmacy team. In this consultation we are proposing to modernise the training of pharmacist independent prescribers to take account of these developments, and to give them the knowledge, attitudes and behaviours they will need to successfully provide high-quality care.

Other important changes in these standards are that we are bringing forward proposals to allow experienced pharmacist independent prescribers (and other prescribers, including doctors) to act as prescribing educational supervisors, and proposals to improve the admissions process by focusing on the knowledge and skills of applicants and their suitability to train as prescribers. We are recommending these changes in response to feedback we have heard from a wide range of stakeholders as part of our preparation for this consultation.

In this consultation, we hope to hear from as many people and organisations as possible about our proposals and we will use what we hear to shape our standards over the coming months.

Nigel Clarke,
Chair, GPhC Council

Duncan Rudkin
GPhC, Chief Executive &
Registrar

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About the GPhC

The General Pharmaceutical Council (GPhC) is the regulator for pharmacists, pharmacy technicians and registered pharmacy premises in England, Scotland and Wales. It is our job to protect, promote and maintain the health, safety and wellbeing of members of the public by upholding standards and public trust in pharmacy.

Our main work includes:

- setting standards for the education and training of pharmacists, pharmacy technicians, and approving and accrediting their qualifications and training;
- maintaining a register of pharmacists, pharmacy technicians and pharmacies;
- setting the standards that pharmacy professionals have to meet throughout their careers;
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public;
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients; and
- inspecting registered pharmacies to check if they are meeting our standards.

Overview

We are consulting until XXXX on standards for the initial education and training of pharmacist independent prescribers. We welcome views from all interested parties but we are especially interested in hearing from current pharmacist independent prescribers, pharmacist independent prescribers in training (hereafter 'trainees'), independent prescribing course providers, pharmacy education and training commissioners and pharmacists who are interested in becoming prescribers.

This consultation document is in three parts:

Section 1: Introduction to the standards;

Section 2: Standards for the initial education and training of pharmacist independent prescribers; and

Section 3: Consultation response form and questions.

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Section 1: Introduction

1.1 Context

Pharmacists have been independent prescribers since 2006 but it is in the last 5-6 years when the demand and opportunities for pharmacist independent prescribers has picked up pace. This is reflected not only in national pharmacy policy initiatives but also in the number of pharmacists applying to train as independent prescribers¹.

Pharmacists working as independent prescribers is part of a wider change in which pharmacy is playing a more significant part in people-facing, front line care. Increasingly, pharmacists are being used to support patients to make the most effective and cost effective use of medicines and also to relieve pressure in critical parts of the healthcare system, particularly in accident and emergency departments and in primary care (for example in GP surgeries, medical centres and care homes).

Although national pharmacy strategies vary, what is consistent across Great Britain is a recognition that employing pharmacist independent prescribers across healthcare settings makes optimal use of pharmacists' prescribing knowledge and skills and that it complements the skill sets of other members of healthcare teams, who are being asked to work together in ever closer ways to create integrated care pathways for people. To achieve this, all three countries have been commissioning places for pharmacists on independent prescribing courses in increasing numbers and, in many places, building in an expectation that independent prescribing training will become a routine part of career development.

There has been a change in the profile of pharmacists training to become independent prescribers since it was introduced in 2006. Initially, interest was from pharmacists with a number of years of clinical practice experience, wanting to add prescribing to an already quite well developed portfolio of clinical and diagnostic skills. More recently, applicants have been younger pharmacists wanting to upskill as prescribers at a much earlier stage in their careers. Alongside this, we are seeing generalist prescribing – in GP practices and emergency departments, in particular – emerging as popular prescribing areas, rather than the more traditional, specialist ones preferred in earlier years. This is a response, in part, to strategic initiatives designed to build generalist pharmacist prescribing capacity in regions across Great Britain.

¹ Conversely, the number of pharmacist supplementary prescribers has not increased and supplementary prescribing courses for pharmacists are no longer offered.

1.2 The pharmacist independent prescriber role

Pharmacists work in a variety of settings and in a variety of ways and this is also the case for pharmacist independent prescribers. While accepting that prescribing practice will vary, at its core is:

... the prescriber takes responsibility for the clinical assessment of the patient, establishes a diagnosis, and the clinical management required as well as the responsibility for prescribing and the appropriateness of any prescribing (National Prescribing Centre, 2005)

We believe that this definition best describes the pharmacist independent prescriber and that education and training courses must be focused on it.

1.3 Key changes

We are proposing three key changes to the education and training of pharmacist independent prescribers:

1. revising the pre-requisite entry requirements for training;
2. introducing learning outcomes; and
3. implementing the introduction of designated prescribing practitioners.

1.3.1 Revising the pre-requisite entry requirements for training

Currently, course applicants must have worked in a patient-facing area² for two years before training to prescribe in that area and must have the relevant pharmacological knowledge and skills to support their prescribing training before they begin the course. What we have heard from some training providers is that there is too much emphasis on the time requirement and not enough emphasis on relevant knowledge and skills. Also, we have no evidence to suggest that time spent working in a particular area produces applicants of the right quality to train.

For these reasons, we propose that the two-year time pre-requisite should be removed, and replaced with a effective but not burdensome application process in which an applicant's experience is verified to ensure that they are ready to train. This does mean that the time required of applicants to demonstrate they have met course pre-requisite entry requirements will vary, depending on their experience and skills, and may be more or less than two years.

² The current wording is 'in a UK hospital, community (pharmacy) or primary care'.

The kind of evidence that would be appropriate to demonstrate an applicant's suitability to train as a prescriber includes:

- i. patient-facing work experience;
- ii. involvement in clinical prescribing led by other prescribers;
- iii. participating in clinical interventions and medicines optimisation activities to improve patient outcomes; and
- iv. participating in multi-disciplinary aspects of prescribing.

The list above is indicative not exhaustive and could reasonably be presented by a pharmacist working with patients in any sector. The ultimate responsibility for checking that an applicant is suitable to train rests with the course provider, as it does now (and as it does for any course of education and training). However, to support consistency across course application processes we will provide guidance on illustrative types of appropriate pre-requisite evidence in a separate document, an evidence framework (see 1.6 Further Work).

From a practical perspective, if these activities have been captured in advance of an application to join a course in continuing professional development (CPD) entries or revalidation activity, they could be used as part of the application evidence base.

We realise that removing the time requirement may concern some people so as an additional safeguard we will add an explicit provision in to our standards that course providers should reject applicants who are not suitably experienced. Having considered the evidence, we have reached the conclusion that removing the time requirement will place the emphasis where it should belong: on the quality of prior experience not the quantity of it.

1.3.2 Introducing learning outcomes

We have introduced new learning outcomes for the pharmacist independent prescribing standards. Introducing learning outcomes brings these standards in to line with contemporary practice and our other standards, which emphasise outcomes – what people can do – rather than inputs.

The learning outcomes will describe the knowledge and skills a trainee should have achieved on successful completion of a course. We believe that they are sufficient to describe what a course must cover, so we do not think it is necessary to produce a detailed syllabus as well. This approach is consistent with our approach to other new sets of education and training standards.

The learning outcomes are general, not specific, and the knowledge and skills in them can be applied in any prescribing area. This means that courses may choose to focus on relatively narrow, specialist area or broader ones, such as general practice or accident and emergency, or both. This reflects the reality of contemporary prescribing practice.

1.3.3 Revising educational supervision requirements for pharmacist independent prescribers in training: from designated medical practitioner to designated prescribing practitioner

Currently, only doctors are allowed to supervise trainees formally as designated medical practitioners (DMPs). In reality, while DMPs sign off trainees, other healthcare professionals offer trainees support and advice, sometimes using their own expertise as prescribers.

We are proposing that in the future, pharmacists training to be independent prescribers could be supervised formally not only by DMPs, but also by experienced pharmacist prescribers and other experienced prescribers. We think it is important that trainees decide what kind of prescribing supervisor they have, in consultation with their course provider. For example, if a trainee thinks that being supervised by a doctor would be most helpful to them then they should be supervised by a doctor, but if they feel that a pharmacist would be more appropriate, that is now an option.

This change would remove a potential barrier to the expansion of the number of pharmacist independent prescribers and alleviate pressure on both course providers and, ultimately, service providers. Giving this responsibility to practising pharmacist independent prescribers would also give them the opportunity to train the next generation and share their experience in the workplace.

In recognition of the change, we plan to alter the DMP title to DPP – Designate Prescribing Practitioner. While the title will change, the role will not: DPPs will sign off trainees as well as assessing their competence in accordance with the requirements of course providers and also giving trainees support and advice. In addition to having a DPP, trainees may continue to draw on the support and advice of other healthcare professionals, including other prescribers.

We will put in place some requirements for the supervisors to make sure they have the necessary skills and experience to be able to effectively supervise, assess the competence of and sign off a trainee (see 1.6 Further Work).

Implementing the change to supervision requirements

We have reflected on this change and we propose to decouple its introduction from the other standards, allowing it to be introduced in advance of new courses based on the full set of standards. The purpose of this is to allow existing courses to expand their pool of prescribing supervisors once the standards have been agreed and revised guidance for them has been issued but without necessarily applying for a full course reaccreditation. Our reasoning is that if a course provider has been reaccredited recently, it would be

unnecessarily burdensome to require them to resubmit again just to permit the introduction of designated prescribing practitioners.

As a safeguard, course providers wanting to introduce the designated prescribing practitioner role in advance of submitting their course for full reaccreditation will be subject to a paper-based, GPhC accreditation exercise focused on just that one change.

1.4 Work undertaken so far to develop the standards

To inform the development of these standards, we have engaged extensively with a range of stakeholders.

In developing them we have taken a wide range of views into account. We began by considering relevant feedback we received from our discussion papers/consultations *Tomorrow's pharmacy team* (2015), *Standards for Pharmacy Professionals* (2016) and *Supervising Independent Prescribers in Training* (2017) and also the results of our survey *Prescribers Survey Report* (2016). More recently we have undertaken over 40 pre-consultation meetings with all schools of pharmacy running independent prescribing courses and other independent prescribing course providers/other stakeholders. The results of these meeting are reflected in the changes we are proposing.

In advance of writing these new standards we decided to issue a discussion paper on one particular aspect of independent prescribing courses: the supervision of pharmacist independent prescribers in training. The results of that discussion paper are presented below in summary.

1.4.1 Supervising independent prescribers in training: discussion paper

At the moment trainees have to be supervised by designated medical practitioners during their training. In 2016 we published a discussion paper *supervising independent prescribers in training*. The full report on our discussion paper consultation can be downloaded [here](#). The proposal we tested in the discussion paper was whether other suitably trained and experienced independent prescribers could be used as supervisors.

The responses we received supported our proposals strongly. Respondents agreed that supervision rights should be extended to suitably experienced pharmacist independent prescribers and also to other suitably experienced independent prescribers. A common theme throughout the responses was the importance of (1) anyone acting as a practice prescribing supervisor being appropriately trained and experienced to act in that role and (2) for people to be trained and supported in their new role. We agree with these points and have built those requirements in to our standards and we will be issuing guidance on being a supervisor as well (see 1.6 Further Work).

We take the responses to mean that there is clear support for our proposals and we have built the provision for non-medical independent prescribers to act as practice prescribing supervisors in to our standards as a separate standard: Part 2 'Domain 9 - Designated prescribing practitioners'. Given the strong level of support for our proposals, we do not intend to re-consult on the principle of changing supervision requirements. We will, however, be asking a question about whether Domain 9 has the relevant safeguards in it to ensure the successful introduction and use of designated prescribing practitioners.

1.4.2 Pre-consultation engagement

In October and November 2017 we held a series of pre-consultation meetings with schools of pharmacy, independent prescribing course providers and other stakeholders. We discussed our proposals for changing supervision and there was broad agreement with what we were proposing. One important caveat put to us by the majority of the people we met was that we should build mechanisms in to our standards for ensuring that designated prescribing practitioners were suitably trained and experienced to act in that role. We have responded to this point by embedding it in the new domain, 9.

Another point raised in the pre-consultation meeting related to the current pre-requisites, which include a requirement that an applicant to an independent prescribing course must have worked in a patient-facing area for two years and have sufficient pharmacological knowledge to form the basis of their prescribing practice while in training. During our pre-consultation meetings it was put to us by course providers that the two-year time requirement was inappropriate, for three reasons:

1. an applicant may have worked in a patient-facing area for two years but may not have gained the knowledge needed to train as an independent prescriber;
2. providers sometimes felt obliged to admit applicants on the basis of time served rather than experience gained; and
3. there was no objective justification for two years (or any other period of time, for that matter).

We have considered these points carefully and think they are important ones. We realise that removing the time requirement might introduce a risk that someone might apply to train before they are ready (or be encouraged to do this) but we think this can be addressed by introducing a much more rigorous requirement for an applicant's experience to be verified to ensure its suitability and relevance and that they are ready to train. We will be bringing forward proposals to make this change.

In addition, it was fed back to us that rather than focusing on an applicant's 'pharmacological knowledge', it would be more appropriate to evaluate their 'clinical and therapeutic experience'. We agree with this, because it emphasizes application of knowledge rather than just knowledge, and have made that change in the standards.

1.5 Links to other prescribing standards and professions

1.5.1 Other standards

The learning outcomes in these standards are based on the prescribing competencies in *A Competency Framework for All Prescribers* (2016) (developed by the Royal Pharmaceutical Society in collaboration with bodies representing all the prescribing healthcare professions). It is a set of competencies for prescribers in practice and, therefore, too broad for prescribers in training. It is, however, a suitable and logical starting point for developing learning outcomes for a course training pharmacist independent prescribers.

In addition, we have taken account of other sets of prescribing standards when drafting ours. In particular, we looked at the new standards proposed in 2017 by the Nursing and Midwifery Council (NMC). In common with us, the NMC are proposing to allow all non-medical prescribers (including pharmacists) to act as prescribing supervisors for nurses in training as prescribers.

1.5.2 Training with other professions

One of the most important aspects of prescribing is its multi-disciplinary nature. It is unusual for a prescriber to prescribe in absolute isolation and, at the very least, must update patient records accessed by other. More commonly, pharmacist prescribing takes place as part of a care package delivered by multiple healthcare professionals. It is for this reason that many pharmacists train as prescribers alongside other healthcare professionals, often nurses, on multidisciplinary training courses. The feedback we have received from pharmacist prescribers is that learning from and with other professionals has been one of the most valuable aspects of their training.

1.6 Further work

1.6.1 Evidence framework

When we wrote our initial education and training standards for pharmacy technicians, we produced an accompanying evidence framework. It provided further information on the standards for course providers and was developed in consultation with them. We will do the same for this set of standards.

It will include further information on:

1. some of the learning outcomes, particularly those that are broad;
2. pre-requisite entry requirements, including examples of appropriate experience; and
3. selecting and quality assuring designated prescribing practitioners.

1.6.2 Guidance for DPPs

We realise that there needs to be guidance for the new designated prescribing practitioners (DPPs) and are in discussions with stakeholders about how best to create it.

The guidance will include:

1. core competencies for DPPs; and
2. guidance for course providers on evaluating the suitability of prospective DPPs.

1.7 Structure and content of the standards

The standards are in two parts:

Part 1: Education and training standards for pharmacist independent prescribers – learning outcomes: this part includes the knowledge, skills, understanding and behaviours required of a pharmacist independent prescriber annotated by the GPhC. As part of this consultation we need to check that the learning outcomes are the right ones and we have asked a question about this.

Part 2: Standards for education and training course providers: This part includes the requirements of a course delivering the learning outcomes in Part 1. As part of this consultation we need to check that these standards are the right ones and we have asked a question about this.

Although they are for different audiences, the two parts are closely linked to each other. This is why they have been presented in one document.

1.7.1 Part 1: Education and training standards for pharmacist independent prescribers – learning outcomes

Part 1 of these standards is presented as learning outcomes - that is the knowledge, skills and attributes a trainee must demonstrate at the end of a course³: as a set, the learning outcomes describe a pharmacist independent prescriber who is fit to practise once annotated.

The learning outcomes have been grouped under four domains, which are:

1. Person-centred care;
2. Professionalism;
3. Professional knowledge and skills; and
4. Collaboration.

The learning outcomes in 'professionalism' and 'collaboration' are more general whereas the learning outcomes in 'professional knowledge and skills' focus on the mechanics of the role and those in 'person-centred care' contextualize the knowledge and skills around the delivery of care, particularly the role that prescribing plays in that.

1.7.2 Linking education and training and practice

Each of the four headings has been linked to standards from *Standards for Pharmacy Professionals*, of which there are nine, to show the link between education and training and practice.

| Person-centred care | | | Professionalism | | Professional knowledge and skills | | Collaboration | |
|---------------------|-------------------------|-----------------------------|------------------------|------------------------|-----------------------------------|-----------------------------------|---------------------|------------|
| Person-centred care | Effective communication | Confidentiality and privacy | Professional behaviour | Professional judgement | Speaking up about concerns | Professional knowledge and skills | Partnership working | Leadership |

In general, the standards refer to 'person-centred care' and refer to a 'person' - this means 'the person receiving care'. However, where it is more appropriate we refer to patients, carers or patients' representatives.

³ Courses of education and training leading to eligibility to register are accredited by the GPhC.

1.7.3 The context of prescribing in training

To train as an independent prescriber, a pharmacist must identify an area of practice in which they will learn to become a prescriber and it must be an area in which they have worked and understand.

While training they will be supervised by another prescriber experienced in that area.

We are not prescriptive about the area in which someone prescribes while training and it could be a specialist one, such as hypertension or HIV, or a more general one, such as prescribing in a GP practice or emergency department.

1.7.4 Part 2: Standards for education and training course providers

Part 2 of the standards focus on the key features of courses that deliver the learning outcomes in Part 1. Pharmacist independent prescriber education and training is delivered in a variety of different ways so it is important to note that the standards have been written in such a way that they are not prescriptive about delivery.

Accepting that delivery and design can be varied, there are three documents required for all courses:

- a teaching and learning strategy, to describe how the learning outcomes in Part 1 will be delivered;
- an assessment strategy, to describe how the learning outcomes in Part 1 will be assessed; and
- a management plan, to describe who is responsible for what in the delivery of a course and the links between learning and work.

In the standards we have been clear about what these documents must contain but in such a way that courses can be delivered, assessed and managed in different ways.

We have taken the same structural approach to Part 2 of the standards by grouping them into domains:

1. Selection and entry requirements;
2. Equality, diversity and inclusion;
3. Management, resources and capacity;
4. Monitoring, review and evaluation;
5. Course design and delivery;
6. Training in practice;
7. Assessment;
8. Training support and the learning experience; and

9. Designated prescribing practitioners.

In each domain there is one or more standards followed by a number of requirements that have to be in place for a standard to be met.

DRAFT

Section 2: Standards for the education and training of pharmacist independent prescribers

Draft standards begin here

Standards for the education and training of pharmacist independent prescribers

About us

The General Pharmaceutical Council regulates pharmacists, pharmacy technicians and registered pharmacies in Great Britain.

What we do

Our main work includes:

- setting standards for the education and training of pharmacists and pharmacy technicians, and approving and accrediting their qualifications and training;
- maintaining a register of pharmacists, pharmacy technicians and pharmacies;
- setting the standards of conduct and performance that pharmacy professionals have to meet throughout their careers;
- setting the standards of continuing professional development that pharmacy professionals have to achieve throughout their careers;
- investigating concerns that pharmacy professionals are not meeting our standards, and taking action to restrict their ability to practise when this is necessary to protect patients and the public;
- setting standards for registered pharmacies which require them to provide a safe and effective service to patients; and
- inspecting registered pharmacies to check if they are meeting our standards.

Introduction

Pharmacists play a vital role in delivering care and helping people to maintain and improve their health, safety and wellbeing. An increasingly central role for pharmacists is that of the independent prescriber. Being an independent prescriber means that you can prescribe a medicine without needing to consult another prescriber before doing so.

Pharmacists cannot prescribe on registration but are required to take an additional course of education and training before they can prescribe. Courses are part-time and are run by universities. A key part of these courses is learning to consult, diagnose and prescribe under the supervision of an experienced prescriber.

Before training to prescribe, pharmacists must have experience of working in a patient-facing context. The area is the one in which the pharmacist will learn how to prescribe. As part of the admissions process an applicant will have to demonstrate that have the right prior knowledge and skills to train as a pharmacist independent prescriber.

These standards describe (1) the knowledge and skills pharmacist independent prescribers will achieve during their education and training and (2) other aspects of the course they will take.

Once a pharmacist has completed successfully their course they can apply to the GPhC for an annotation to their entry in the GPhC's Register. The annotation is a public record that they can practise as an independent prescriber.

Hereafter pharmacist independent prescribers in training will be called 'trainees'.

The prescribing role

Prescribing will be applied in different ways and in different contexts but at its core will be the following:

... the prescriber takes responsibility for the clinical assessment of the patient, establishes a diagnosis, and the clinical management required as well as the responsibility for prescribing and the appropriateness of any prescribing (National Prescribing Centre, 2005)

On successful completion of an independent prescribing course trainees must have demonstrated this.

The structure of the standards

The standards for the education and training of pharmacist independent prescribers are in two parts: 1. learning outcomes and 2. standards for independent prescribing course providers.

Part 1, the learning outcomes, describes what a trainee will be able to do on successful completion of the course. The learning outcomes are presented in four domains:

1. Person-centred care;
2. Professionalism;
3. Professional knowledge and skills; and
4. Collaboration.

Part 2, the standards for independent prescribing course providers, describes the requirements for any course provider and also pre-requisites for entry to a course. The standards have nine domains:

1. Domain 1 – Selection and entry requirements;
2. Domain 2 – Equality, diversity and inclusion;
3. Domain 3 – Management, resources and capacity;
4. Domain 4 – Monitoring, review and evaluation;
5. Domain 5 - Course design and delivery;
6. Domain 6 – Training in practice;
7. Domain 7 – Assessment;
8. Domain 8 – Support and the learning experience; and
9. Domain 9 – Designated prescribing practitioners.

Part 1: Education and training standards for pharmacist independent prescribers – learning outcomes

Standard: On successful completion of their education and training, trainees will have achieved the learning outcomes in these standards.

Level of study

The level of study for pharmacist independent prescriber courses is Master's level⁴, as defined in GB national qualifications frameworks.

Minimum learning time requirements

While teaching, learning and assessment are matters for course providers, as a minimum there must be:

1. at least 26 days of structured learning activities; and
2. at least 90 hours of learning in practice.

Learning activities: 'Learning activities' are defined by course providers. They can include in-class work, directed study, self-directed study and distance learning activities.

Learning in practice: 'Learning in practice' time is when trainees practise and develop their clinical, diagnostic and prescribing skills under the supervision of other healthcare professionals, including their designated prescribing practitioner (who is responsible for signing off a trainee as being a competent prescriber in the area they have trained).

Domains of study

Learning outcome are presented under four domains:

5. Person-centred care;
6. Professionalism;
7. Professional knowledge and skills; and
8. Collaboration.

The domains and learning outcomes are not hierarchical and have equal importance.

⁴ The majority of current prescribing courses are at Master's level already.

Learning outcomes

In these standards Miller's Triangle is used to set the outcome level: Miller's triangle is a knowledge and competence hierarchy describing four levels of outcome: 'knows' (knowledge), 'knows how' (application of knowledge), 'shows how' (demonstrate competence in a limited way) and 'does' (demonstrates competence repeatedly and safely). The outcomes in these standards have been set at the right level for trainees.

The learning outcomes are:

Domain 1: Person-centred care

| Pharmacist independent prescribers in training will be able to: | Level |
|---|--------------|
| 1. Understand the psychological and physical impact of prescribing decisions on people | Knows how |
| 2. Recognise diversity and the values and beliefs of people when making prescribing decisions, | Does |
| 3. Demonstrate appropriate history-taking techniques to get information when making informed decisions about a variety of people with simple and complex conditions | Does |
| 4. Understand the role of the prescriber in making decisions about people who may not be able to make fully informed decisions about their health needs. | Knows how |
| 5. Work with patients/carers/patient representatives to make informed choices that respect patients' preferences | Does |

Domain 2: Professionalism

| Pharmacist independent prescribers in training will be able to: | Level |
|---|--------------|
| 6. Demonstrate a critical understanding of their own role and the role of others as prescribers and how this role contributes to multi- professional team providing person-centred care | Does |
| 7. Recognise own role as a responsible and accountable prescriber who understands legal and ethical implications | Does |
| 8. Understand the legislation and ethical frameworks related to prescribing | Knows how |
| 9. Recognise and manage factors that may unduly influence prescribing decisions | Does |
| 10. Understand the ethical frameworks and legislation in sharing confidential information | Knows how |
| 11. Understand the legal and ethical frameworks and risks in prescribing via remotely (including online) | Knows how |
| 12. Apply local, regional and national guidelines, policies and legislation related to healthcare | Does |

| | |
|--|-----------|
| 13. Reflect and develop their own prescribing practice to ensure it represents current best practice | Does |
| 14. Demonstrate an understanding of health economics when making prescribing decisions | Does |
| 15. Understand the clinical governance of the prescriber who may also be in a position to supply medicines to people | Knows how |

Domain 3: Professional knowledge and skills

| Pharmacist independent prescribers in training will be able to: | Level |
|---|--------------|
| 16. Apply evidence-based decision making in all aspects of prescribing, de-prescribing and non-pharmacological interventions | Does |
| 17. Demonstrate a critical understanding of pharmacological, pharmacokinetic and pharmacodynamic effect of medicines and devices when making prescribing decisions | Does |
| 18. Demonstrate clinical and diagnostics skills in clinical settings appropriate to their training | Does |
| 19. Demonstrate an understanding of the importance of accurate record keeping and relevant legislation | Does |
| 20. Interpret relevant investigations, results and data to make decisions about people | Does |
| 21. Understand the range of systems available to prescribe medicines in different clinical settings | Knows how |
| 22. Apply the principles of effective monitoring and management to improve patient outcomes | Does |
| 23. Demonstrate a comprehensive understanding of side effects, contra-indications and adverse drugs reactions of medicines within their prescribing practice focused on person-centred care | Does |

Domain 4: Collaboration

| Pharmacist independent prescribers in training will be able to: | Level |
|---|--------------|
| 24. Work constructively with other healthcare professionals, understanding their roles in the prescribing process | Does |
| 25. Recognise other professionals' practice and raise concerns where inappropriate or unsafe prescribing occurs | Does |
| 26. Understand own role and responsibilities and those of others in safeguarding children and vulnerable adults | Knows how |
| 27. Understand when and where to refer people appropriately | Knows how |
| 28. Collaborate with patients/carers/patient representatives to encourage them to take responsibility for managing conditions | Does |
| 29. Implement appropriate communications techniques to elicit information from individuals who are unaware or non-complicit about their circumstances | Does |

| | |
|---|------|
| 30. Recognise when to refer or seek guidance from another member of the healthcare team, specialist or appropriate authority. | Does |
|---|------|

Part 2: Standards for pharmacist independent prescribing course providers

Part 2 comprises prerequisites for entry to a pharmacist independent prescriber course followed by nine standards and associated criteria.

Pre-requisites for entry

1. The pre-requisites for entry to a pharmacist independent prescriber course are that:
 - 1.1 Applicants are registered as a pharmacist with the General Pharmaceutical Council (GPhC) or, in Northern Ireland, with the Pharmaceutical Society of Northern Ireland (PSNI).
 - 1.2 Applicants are in good standing with the GPhC and/or PSNI and any other healthcare regulator with which they are registered.
 - 1.3 Applicants have an identified area of clinical/therapeutic practice in which to develop independent prescribing practice and have relevant clinical/therapeutic experience in that area, which is suitable to act as the foundation of their prescribing practice while training.
 - 1.4 Applicants must present their relevant clinical and therapeutic experience as part of the application process. The relevance of an applicant's experience to the requirements of the course must be evaluated by providers as part of the application process. Providers must reassure themselves that applicants have the right prior knowledge and skills to train as a pharmacist independent prescriber.
 - 1.5 Applicants must have secured a designated prescribing practitioner who has agreed to supervise the applicant's learning in practice. A designated prescribing practitioner is an independent prescriber who is suitably experienced and qualified to undertake a supervisory role on an independent prescribing course. Note that while an applicant may be supervised and mentored by more than one person, one prescriber must be the designated prescribing practitioner. The designated prescribing practitioner is the person who will certify that pharmacists are competent to practise as independent prescribers on successful completion of the course.
 - 1.6 The applicant's designated prescribing practitioner must be a registered healthcare professional in Great Britain or Northern Ireland with legal independent prescribing rights. Professionals with such rights include pharmacists, doctors, dentists and nurses.

- 2.1 Course providers must ensure that all the pre-requisites have been met before the commencement date of a course on which an applicant is enrolled.
- 2.2 If having fully evaluated an application, a course provider decides that a pharmacist is not sufficiently experienced to train as an independent prescriber, the application should be rejected, with reasons.

Domain 1 – Selection and entry requirements

Standard 1: Selection processes must be open, clear, unbiased, comply with relevant legislation and ensure that applicants meet course pre-requisites for entry.

Criteria to meet these standards

- 1.1 Selection criteria must be clear and must include meeting all the pre-requisites for entry in these standards.
- 1.2 Selectors must apply the selection criteria consistently, in an unbiased way and in a way compatible with relevant legislation.
- 1.3 Course providers must provide clear guidance on the type of experience a pharmacist should have before applying to the course. This guidance must be available to applicants in advance of them making an application.

Domain 2 – Equality, diversity and inclusion

Standard 2: All aspects of pharmacist independent prescribing education and training must be based on principles of equality and diversity and be compatible with all relevant legislation.

Criteria to meet this standard

- 2.1 Equality and diversity must be embedded in course design and delivery.
- 2.2 Equality and diversity data must be used to inform course design, delivery and the learning experience.
- 2.3 Reasonable adjustments must be made to course delivery to help trainees with specific needs to meet the learning outcomes.
- 2.4 Teaching, learning and assessment can be modified for the purpose stated in 2.3 but learning outcomes cannot.

Domain 3 – Management, resources and capacity

Standard 3: Courses must be planned and maintained through transparent processes which must show who is accountable for what. The education and training facilities, infrastructure, leadership, staffing and staff support must be sufficient to deliver the course.

Criteria to meet this standard

3.1 All courses must be underpinned by a defined management plan which must include:

- a schedule of roles and responsibilities in learning/teaching/practice environments;
- lines of accountability in the learning/teaching/practice environments;
- defined structures and processes to manage delivery; and
- processes for identifying and managing risk.

3.2 There must be agreements in place outlining the roles and responsibilities of all those involved in delivering a course.

3.3 Learning agreements must be in place with the trainee in all learning/teaching/practice environments outlining roles and responsibilities and lines of accountability.

3.4 In all learning/teaching/practice environments, there must be:

- appropriately qualified and experienced professionals;
- sufficient staff from relevant professions to deliver the course and support the learning of pharmacist independent prescribers in training;
- sufficient resources available to deliver the course;
- facilities that are fit for purpose; and
- access to appropriate learning resources.

3.5 All those involved in managing and delivering the course must understand their role and must be supported to carry out their work effectively.

3.6 Each trainee must be supported as a learner in learning in practice environments and there must be mechanisms in place for liaising with course providers regularly about the progress of a trainee in learning in practice environments.

Domain 4 – Monitoring, review and evaluation

Standard 4: The quality of a course must be monitored, reviewed and evaluated in a systematic and developmental way.

Criteria to meet this standard

4.1 All relevant aspects of a course must be monitored, reviewed and evaluated systematically. When issues are identified they must be documented and addressed within agreed timescales.

4.2 There must be a quality management structure in place that sets out procedures for monitoring and evaluation including who is responsible and timings for reporting, review and taking action where appropriate.

4.3 There must be procedures in place to monitor and evaluate the standard of teaching, learning and assessment to ensure that quality is maintained across all learning environments.

4.4 Course monitoring and review must take into account the external environment, especially pharmacy, to ensure that courses remain up-to-date as they are delivered.

4.5 Feedback to pharmacist independent prescribers in training must be embedded in monitoring, review and evaluation processes.

4.6 A course must have been validated by the providing institution before applying for GPhC accreditation.

Domain 5 – Course design and delivery

Standard 5: Courses must develop the behaviours, required skills, knowledge and understanding to meet the outcomes in Part 1 of these standards through a coherent teaching and learning strategy.

Criteria to meet this standard

5.1 There must be a course teaching and learning strategy which sets out how pharmacist independent prescribers in training will achieve the outcomes in the Part 1 of these standards.

5.2 Courses must be designed and delivered through strategies which integrate prescribing knowledge and skills, including clinical and diagnostic skills, with the pre-existing experience of trainees as pharmacists.

5.3 All course providers must have pharmacy professionals, including pharmacist independent prescribers, involved in the design and the delivery of the course.

5.4 Course providers must engage with a range of stakeholders, including patients, the public, course commissioners and employers, to inform the design and delivery of the course.

5.5 Courses must be updated when there are significant changes in practice to ensure they are current.

5.6 Trainees must only undertake tasks in which they are competent, or are learning to be competent, so that patient safety is not compromised.

5.7 Trainees must be supervised through agreed mechanisms in all clinical practice environments to ensure safe person-centred care is delivered at all times.

5.8 Course regulations must be appropriate for a course that leads to professional annotation, that is they must prioritise patient safety, safe and effective practice and clinical skills.

5.9 There must be systems in place to ensure that trainees understand what fitness to practise mechanisms apply to them. All course providers and employers must have procedures to deal with fitness to practise concerns.

5.10 Causes for concern about a trainee, supervising independent prescribers or the learning environment must be addressed as soon as possible and in such a way that the cause for concern is addressed.

Domain 6 – Learning in practice

Standard 6: Courses must develop the behaviours, required skills, knowledge and understanding to meet the outcomes in Part 1 of these standards in learning in practice settings.

6.1 Part of the course must take place in clinical settings with direct access to patients – these are ‘learning in practice’ settings.

6.2 In the learning in practice settings identified in 1.3, trainees will prescribe under the supervision of a designated prescribing practitioner.

6.3 Where more than person is involved in the supervision of a trainee, one independent prescriber must assume primary responsibility for the trainee's supervision: that person will be the designated prescribing practitioner for the trainee.

6.4 Course providers must agree a designated prescribing practitioner with a prospective trainee and must agree that the designated prescribing practitioner that they have the core competencies to undertake the role effectively.

6.5 The designated prescribing practitioner is responsible for signing off a trainee as being competent as a pharmacist independent prescriber.

Domain 7 – Assessment

Standard 7: Courses must have an assessment strategy which assesses the professional behaviours, required skills, knowledge and understanding to meet the outcomes in Part 1 of these standards. The assessment strategy must assess whether the practice of a pharmacist independent prescribers in training is safe.

Criteria to meet this standard

7.1 Courses must have an assessment strategy which ensures that assessment is robust, reliable and valid.

7.2 Course providers are responsible for ensuring that all learning outcomes are assessed fully through appropriate methods and that teaching and learning is aligned with assessment.

7.3 Patient safety must be paramount at all times and the assessment strategy must assess whether a trainee is practising safely.

7.4 Monitoring systems must be in place in all learning environments. The systems must assess the progress of a trainee toward meeting the learning outcomes in Part 1 of these standards and must ensure that the practice of a trainee is safe at all times.

7.5 Agreements must be in place between course providers and designated prescribing practitioners describing roles and responsibilities in the assessment of trainees.

7.6 Assessments must be carried out by appropriately trained and qualified people who are competent to assess the performance of trainees.

7.7 Irrespective of their location, all assessments must be quality assured by course providers.

7.8 Trainees must receive appropriate and timely feedback on their performance to support their development as learners.

7.9 Assessment regulations must be appropriate for a course that leads to professional annotation and must prioritise patient safety, safe and effective practice and clinical and diagnostic skills.

7.10 All summative assessments must be passed.

7.11 On patient safety grounds, compensation or condonation are not allowed on courses for pharmacist independent prescribers in training.

7.12 Unsafe practice demonstrated by trainees must not be passed.

Domain 8 – Support and the learning experience

Standard 8: Trainees must be supported in all learning environments to develop as learners during their training.

Criteria to meet this standard

8.1 A range of mechanisms must be in place to support trainees to achieve the learning outcomes in Part 1 of these standards, including:

- induction;
- effective supervision;
- an appropriate and realistic workload;
- personal and academic support; and
- access to resources.

8.2 There must be mechanisms in place for trainees to meet regularly with their designated prescribing practitioner and others to discuss and document their progress as learners.

8.3 There must be clear procedures for trainees to raise concerns. Any concerns must be dealt with promptly, with documented action taken where appropriate.

8.4 Everyone supporting trainees must take into account the GPhC's *Guidance on tutoring for pharmacists and pharmacy technicians* in their work as appropriate.

Domain 9 - Designated prescribing practitioners

Standard 9: Designated prescribing practitioners must be fit to undertake that role and must have appropriate training and experience.

Criteria to meet this standard

9.1 Course providers must have appropriate mechanisms for ensuring that designated prescribing practitioners are fit to be the prescribing supervisors of trainees.

9.2 Prospective designated prescribing practitioners must have:

- current prescribing competence in the areas in which they will be supervising;
- mentored/supervised other healthcare professionals;
- appropriate clinical and diagnostic skills; and
- assessed clinical and diagnostic competence.

9.3 Course providers must provide training for designated prescribing practitioners in the following areas:

- the pharmacist independent prescribing role;
- the course for trainees on which they will be working, including its learning outcomes;
- the role of designated prescribing practitioners in the course;
- assessing the performance of trainees;
- giving feedback to trainees;
- supporting trainees; and
- raising concerns.

9.4 Course providers must support new designated prescribing practitioners when they are acting in that role by providing them with a mentor, at least for the first iteration of the course when they are acting as prescribing supervisors (and for longer if necessary). Mentors will be familiar with the course and the designated prescribing practitioner role in the context of the course.

9.5 Course providers must provide designated prescribing practitioners with feedback about their performance as prescribing supervisors and arrange additional training, support and or development as necessary.

Section 3: Responding to the consultation

3.1 The consultation process

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 www.pharmacyregulation.org/XXX and fill in an online version there.

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

consultations@pharmacyregulation.org with the subject 'PIP standards consultation'

or post it to us at:

**PIP Standards Consultation response
Education Team
General Pharmaceutical Council
25 Canada Square
London E14 5LQ**

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to:

feedback@pharmacyregulation.org

or post them to us at:

**Governance Team
General Pharmaceutical Council
25 Canada Square
London E14 5LQ**

Please do not send consultation responses to this address.

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive. Our governing Council will receive the analysis at a meeting in the second half of 2018. It will take the responses into account when considering the final ET standards for pharmacist independent prescribers.

We will also publish a summary of the responses and an explanation of the decisions taken. You will be able to see this on our **website www.pharmacyregulation.org**

3.2 Consultation response form

Response to the consultation on education and training standards for pharmacist independent prescribers

If you want your response to stay confidential, please explain why you think the information you have given is confidential. 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 our 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 member of the public

a pharmacy professional – please go to Section A1

a pharmacist pre-registration trainee

a pharmacy technician trainee

a pharmacy student

other (please give details)

Section A1 – Pharmacy professionals

Are you:

a pharmacist

a pharmacy technician

In which of these areas do you work?:

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)

How we will use your responses

All responses will be analysed and will form the basis of a report to our Council. It will be discussed and will form the basis of a revised version of the standards which will then be presented to our Council for consideration and approval. We anticipate presenting a revised set of standards in Autumn 2018.

If you would like your response to be anonymous please check this box ☐

DRAFT

Consultation questions

Section 1: Learning outcomes

As part of this revision of the initial education and training standards for pharmacy technicians, we have developed a set of learning outcomes which should describe the right knowledge, skills and attributes of a pharmacist independent prescriber.

Q1a: Considering the full set of learning outcomes in Part 1 of these draft education and training standards, to what extent do you agree that these are appropriate learning outcomes for a pharmacist independent prescriber in training?

Strongly agree / Partially Agree / Neither agree nor disagree / partially disagree / strongly disagree

Q1b: Please explain your response

Q2a. Is there anything missing from the learning outcomes in Part 1?

Y/N/Don't know (No/Don't know, go to question 3a)

Q2b: In which of the following areas do you think there is something missing? (Please tick all that apply)

Person-centred care

Professionalism

Professional knowledge and skills

Collaboration

Other

Q2c: Please provide a brief description of the gap(s) you have identified

Q3a: Is there anything in the learning outcomes in Part 1 that should be removed?

Y/N/Don't know (No/Don't know, go to question 4a)

Q3b: Please provide details of the learning outcomes you would remove and why (where possible, please state the reference number of the learning outcome(s))

Section 2: Standards for course providers

As part of this revision of the initial education and training standards for pharmacist independent prescribers, we have written a set of standards for course providers. The purpose of the standards is to describe the requirements that underpin courses delivering the learning outcomes in Part 1 of the standards.

Q4: Considering the full set of standards and criteria in Part 2, to what extent do you agree that these are appropriate standards for a pharmacist independent prescriber education and training course?

Strongly agree / Partially Agree / Neither agree nor disagree / partially disagree / strongly disagree

Q1b: Please explain your response

Q5a. Is there anything missing from the standards or criteria in Part 2?

Y/N/Don't know (No/Don't know, go to question 6)

Q5b: In which of the following areas do you think there is something missing? (Please tick all that apply)

Domain 1 – Selection and entry requirements
Domain 2 – Equality, diversity and inclusion
Domain 3 – Management, resources and capacity
Domain 4 – Monitoring, review and evaluation
Domain 5 – Course design and delivery
Domain 6 – Learning in practice
Domain 7 – Assessment
Domain 8 – Support and the learning experience
Domain 9 – Designated prescribing practitioners
Other

Q5c: Please provide a brief description of the gap(s) you have identified.

Q6a: Is there anything in the standards or criteria in Part 2 that should be removed?

Y/N/Don't know (No/Don't know, go to question 7)

Q6b: Please provide details of the standards or criteria you would remove and why (where possible, please state the standard or criteria reference number).

Supervising pharmacist independent prescribers in training

In a discussion paper issued in November 2016 we asked whether the role of Designated Medical Practitioner should be expanded to allow suitably experienced and qualified non-medical independent prescribers to act as supervisors for the training in practice part of pharmacist independent prescribing courses. The questions we asked were (1) whether supervision rights should be extended to experienced pharmacist independent prescribers and (2) whether they should be extended to other experienced independent prescribers?

The responses have been laid out in this consultation document but in summary there was strong agreement with the first proposal and clear agreement with the second. With that mandate we have written a new standard, Standard 9, for an expanded group of supervisors - Designated Prescribing Practitioners.

Q7a: Will Standard 9 ensure that only appropriately trained and experienced independent prescribers will be acting as designated supervisors on education and training courses for pharmacist independent prescribers?

Y/N/Don't know

Q7b: Please explain your response

Prerequisites for training

One of the current pre-requisites for training as a pharmacist independent prescriber is that someone must have worked in a patient-facing context for at least two years, when they should have acquired the clinical and diagnostic experience they need to then train to prescribe in that area. During our pre-consultation meetings it was put to us by independent prescribing course providers that the two-year time requirement was inappropriate, for three reasons:

1. an applicant may have worked in an area for two years but may not have gained the knowledge needed to train as an independent prescriber;
2. providers sometimes felt obliged to admit applicants on the basis of time served rather than experience gained; and
3. there was no objective justification for two years.

We accept these points and propose to remove the current two-year time pre-requisite for training replace it with a requirement for the suitability and relevance of an applicant's experience for be submitted and verified as part of the application process.

Q8a: Should the current two-year time pre-requisite for training be removed and replaced with a requirement for the suitability and relevance of an applicant's experience to be submitted and approved as part of the application process?

Y/N/Don't know

Q8b: Please explain your response

Impact of the standards

We want to understand whether our standards may discriminate against or unintentionally disadvantage any individuals or groups sharing any of the protected characteristics in the *Equality Act 2010*. These characteristics are:

- Age;
- Disability;
- Gender reassignment;
- Marriage and civil partnership;
- Pregnancy and maternity;
- Race;
- Religion or belief;
- Sex; and
- Sexual orientation.

Q9a: Do you think anything in the standards or proposed changes would impact – positively or negatively – on certain individuals or groups who share any of the protected characteristics listed above?

Y/N/Don't know (No/Don't know, go to Q10)

Q9b Please describe the impact and the individuals or groups concerned

Q10a: Do you think anything in the standards or proposed changes would impact – positively or negatively – on any other individuals or groups?

Y/N/Don't know (No/Don't know, go to Q10)

Q10b Please describe the impact and the individuals or groups concerned

Other comments

Q11: Are there any other comments you would like to make about these standards or the changes we are proposing?

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 standards for pharmacy professionals. 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
- ☐ White and Asian
- ☐ other mixed (please give more information in the box below)

Asian or Asian British

- ☐ Indian
- ☐ Pakistani
- ☐ Bangladeshi
- ☐ other Asian (please give more information in the box below)

☐ 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 religion?

Please tick one box

☐ None

☐ Christian

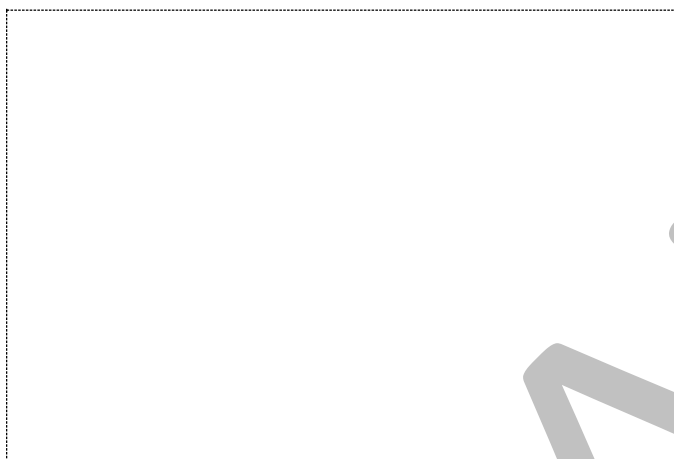
☐ Buddhist

☐ Hindu

☐ Jewish

☐ Muslim

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



Do you consider that you have a disability?

Please tick one box

☐ Yes

☐ No

Consultation on education and training standards for pharmacist independent prescribers: equality impact assessment

EA completed by:

Signed: Juliette Becuwe **Date:** 10.01.2018

Name: Juliette Becuwe, Policy Officer **Date:** 12.01.2018

EA approved by:

Signed:  **Date:** 22.01.2018

Name: Damian Day, Head of Education **Date:** 22.01.2018

1. Aims and purpose of the project/policy

1.1 This equality impact analysis (EIA) focuses on the equality and diversity implications of proposed changes from the review of the standards for the education and training of pharmacist independent prescribers (the standards) – previously called the accreditation criteria, learning outcomes and indicative content for pharmacist independent prescribing programmes.

1.2 As part of the review of the standards, we also sought feedback on the following proposed changes:

- Changing the practice supervision requirements to allow other non-medical independent prescribers, as well as designated medication practitioner (DMPs) to supervise pharmacists training to become independent prescribers, in practice, and
- Removing the pre-requisite entry requirement that pharmacists must have two years' experience of working with patients before they can apply for an independent prescribing programme.

- 1.3 Domain 2 of our revised standards includes a separate domain dedicated to equality and diversity. This aims to ensure that course developers and providers collect and consider equality and diversity data, including those related to the protected characteristics, and demonstrate how it is used to continually inform and influence the design and delivery of their courses.
- 1.4 The EIA aims to help ensure that our future standards do not unfairly affect groups with protected characteristics¹. It focuses on how protected characteristics have been considered in the standards development process and especially through our stakeholder engagement. In carrying out this analysis, we have considered the potential equality and diversity implications of the revised standards.
- 1.5 We aim to be proactive in facilitating opportunities for people with the widest possible range of experience and perspectives to engage with our work, and by doing so to ensure that we are not acting in a way that is incompatible with a Convention right² and meeting our Public Sector Equality Duty under the Equality Act 2010³. To meet Section 149 of the Equality Act 2010 we have due regard to each of the following statutory objectives:
- Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act
 - Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it, and
 - Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- 1.6 In preparing this analysis, we have considered all of the statutory objectives under Section 149 of the Equality Act 2010.
- 1.7 The EIA includes an overview of the work we have completed to inform our understanding of the equality and diversity dimensions of the proposed changes. We aimed to identify any trends or issues that apply to people who share protected characteristics and considered potential negative impacts on these groups.
- 1.8 The EIA has will be informed by our quantitative and qualitative analysis of responses to the consultation; the available data and/or evidence relating to groups of people with protected characteristics; and, our extensive engagement with a wide variety of stakeholders. The analysis assists Council to consider whether the changes to the standards should be approved and/or subject to further amendment before introduction.
- 1.9 We sought to identify and mitigate any adverse impact on groups of people with a protected

¹ The Equality Act 2010 prohibits direct or indirect discrimination, or harassment on the basis of a protected characteristic (age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion and belief, sex and sexual orientation). There is a fundamental distinction between direct discrimination, on the one hand, and indirect discrimination on the other (Sections 13 and 19). Direct discrimination is where an individual receives less favourable treatment because of a protected characteristic. Indirect discrimination concerns a provision, criterion or practice that puts someone with a protected characteristic at a particular disadvantage, compared with people who do not share the protected characteristic (Section 19). However, a provision, criterion or practice that causes a particular disadvantage is lawful if it is a proportionate means of achieving a legitimate aim.

² The Human Rights Act 1998, Section 6f

³ The Equality Act 2010, Section 149

characteristic. This includes future pharmacist independent prescribers, people involved in their education and patients or members of the public interacting with them and using their services.

Policy context

- 1.10 The delivery of healthcare has been changing quickly in response to the needs of a changing population. The population is growing and getting older, with health needs that are getting more complicated. This is adding to the demands on, and the cost of, national health services. Governments across the UK have highlighted the need for the healthcare workforce to develop and adapt to meet these demands, and this includes the pharmacy workforce.
- 1.11 Government policies across the UK have specifically highlighted the important role of pharmacists in general and the importance of non-medical prescribing. Doctors used to be the only healthcare professionals allowed to prescribe. The 1999 Crown Review proposed that as pharmacists and nurses had an appropriate level of knowledge and skills they should be allowed to prescribe medicine. This recommendation was accepted by government and by 2003 pharmacist supplementary prescribing was allowed. By 2006 pharmacist independent prescribing was also allowed.
- 1.12 Independent prescribing allows prescribers to prescribe without consulting another prescriber, whereas supplementary prescribing only allow prescribers to prescribe within a patient-specific clinical management plan drawn up by another prescriber, usually a doctor.
- 1.13 The Royal Pharmaceutical Society of Great Britain (RPSGB), then the regulator for pharmacists in GB, defined the education and training that pharmacist prescribers would need, based on broad guidelines from the Department of Health (DH). The RPSGB began to accredit courses that would lead to pharmacists having an 'annotation' on its register as either a supplementary or an independent prescriber.
- 1.14 Interest in supplementary prescribing has decreased sharply over the years and we are no longer accrediting courses. We accredit reconversion courses to independent prescribing. Our review only focuses on pharmacist independent prescribing because all the signs show that it is the independent role not the supplementary one that will grow in the future. The number of pharmacist independent prescribing courses continues to increase. There are now 45 accredited pharmacist independent prescribing courses in the UK.
- 1.15 Governments across the UK encourage pharmacists to train and practise as pharmacist independent prescribers. The different countries governments' healthcare agendas and funding priorities have had an influential trend in applicants and workplaces in their respective countries. The Northern Irish Government committed to increase the number of pharmacist independent prescribers in GP practices and provided the associated funding to support that commitment⁴. Similarly, both the English and Scottish Governments have highlighted how independent prescribing can contribute to public health and provided support to increase the number of healthcare professionals training as an independent prescriber⁵.

⁴ The former Minister of Health in the Northern Ireland Government announced in 2015 a five year initiative to increase the number of pharmacists in GP practices. [Minister announces investment to put pharmacists in GP practices](#), Northern Ireland Government, December 2015.

⁵ To support the implementation of NHS England's [Five Year Forward View](#), the English Government has created a [Pharmacy Integration Fund](#) to support one of the English Government's priorities to deploy more clinical pharmacists and pharmacy services in community and primary care including groups of general practices, care homes and urgent care settings. The

- 1.16 Prior to consulting on new standards we issued a discussion paper on the supervision of pharmacist prescribers in training. This consultation sought feedback on the proposal to change the practice supervision requirements to allow other non-medical independent prescribers, as well as DMPs to supervise pharmacists training to become independent prescribers, in practice. This initial consultation ran between November and February 2017⁶. We sent the discussion papers to other health professional regulators (particularly those who regulate prescribers), funders of health education and training, professional representative bodies, employers, education and training providers, and patients' representative bodies.
- 1.17 We analysed the discussion paper responses⁷ and conducted further stakeholder engagement⁸, incorporated comments in our revised standards before we launch a consultation on our revised standards for the education and training of pharmacist independent prescribers.
- 1.18 Once we have finalised the standards, we will take steps to engage with course providers and prepare to accredit and quality assure courses leading to annotation. As part of the accreditation and quality assurance process, course providers are responsible for providing evidence showing how they meet or apply each of our standards to gain accreditation. This is one of the ways we assure the implementation of the new standards, including standards specifically focusing on equality and diversity aspects.
- 1.19 We will also be producing a supporting evidence framework which will provide practical examples for course designers and developers about the type of evidence that could be provided through the accreditation process. This document will also assist in ensuring consistent interpretation of the new standards.
- 1.20 In addition, as part of the monitoring of the implementation of the standards we are also committed to a review our quality assurance and accreditation process.

2. Review of available information and/or data

Developing our evidence-base

- 2.1 We have carried out a systematic and evidence-based approach to our policy development, including an assessment of the equality and diversity dimensions of our proposals.
- 2.2 Through our evidence gathering we have identified certain areas where it would be beneficial to gather more evidence and data to inform policy development, as there are gaps in comparison to the data we collect on future pharmacists. As the annotation of prescribers on our register is relatively new, the available data in relation to equality and diversity indicators has been limited.

Scottish Government also published their report, Prescription for Excellence, in 2016 as well as the revised version in 2017, [Achieving Excellence in Pharmaceutical Care](#) which set out their vision of pharmacy in the future, including an increase in independent prescribing roles for pharmacists.

⁶ [GPhC seeks views on supervising independent prescribers in training](#)

⁷ Supervising pharmacist independent prescribers in training: Summary of responses to the discussion paper

⁸ Standards for the education and training of pharmacist independent prescribers, Summary of findings: independent prescriber pre-consultation engagement

- 2.3 We will reformulate the question we ask in regard to impact on equality and diversity in our future consultations as we noticed that survey respondents often struggled to respond to this question in regard to protected characteristics and that it was difficult for us to exploit their responses.

Legal framework

- 2.4 Article 4(3) of the Pharmacy Order 2010 sets the principal functions of the Council. In regard to education its role is:

*(e) to set standards and requirements in respect of the education, training, acquisition of experience and continuing professional development that it is necessary for pharmacists and pharmacy technicians to achieve in order to be entered in the Register **or to receive an annotation in the Register** and to maintain competence.*

- 2.5 Article 27 focuses on specialisations for registrants and registered pharmacies.

(1) The Council may make such provision in rules as it considers appropriate in connection with annotations to entries in the Register to denote specialisations, and may in particular make provision with regard to:

- (a) the type of specialisations that are to be subject to annotations;*
- (b) the form and manner in which applications for entering, renewing or restoring annotations in respect of specialisations, or for the removal of such annotations, are to be made (and the rules may provide that applicants must apply using application forms that are in such form as the Council may determine from time to time);*
- (c) the circumstances in which annotations in respect of specialisations are to be entered, renewed, restored or removed by the Registrar;*
- (d) the removal of annotations in respect of specialisations by the Registrar where a prescribed fee in respect of the renewal of the annotation has not been paid, after such warnings as may be prescribed;*
- (e) the standards of proficiency for the safe and effective practice of pharmacy that it is necessary for a registrant to achieve in order for an annotation in respect of a specialisation to be made to an entry in the Register of a registrant.***

- 2.6 We can approve prescribing courses because under article 42(4). The Council may:

- (b) Approve, or arrange with others to approve such other courses of education or training as the Council considers appropriate;*
- (c) approve, or arrange with others to approve, qualifications which are granted following success in an examination, or some other assessment, taken as part of an approved course;*
- (e) approve, or arrange with others to approve—*
 - (i) institutions,*
 - (ii) other providers, including tutors,**of postgraduate education and training which leads to an approved qualification, if the Council considers that they are properly organised and equipped for conducting the whole or part of an approved course;*
- (f) approve, or arrange with others to approve, premises as being suitable for postgraduate*

education and training which leads to an approved qualification.

2.7 Article 42(6)(b) also stipulates that Council must publish a statement of:

(b) the criteria that will be taken into account in deciding whether to grant approval under paragraph (4), as they exist from time to time”.

2.8 Finally, Article 42(7) states that:

The Council must publish and maintain a list of the courses of education and training, qualifications and institutions or other providers (including tutors)

(a) which are for the time being approved under this Order; or

(b) which have been approved under this Order but which are no longer so approved, together with a record of the periods in respect of which approval was given.

2.9 In developing the standards we also gave due regard to our statutory objectives under Section 149 of the Equality Act 2010 and we believe that the proposals align with our overarching legal objective which is the protection of the public⁹.

Other standards pharmacists independent prescribers have to adhere to

2.10 It is important to note that pharmacist independent prescribers have to adhere to other standards because of their registration as pharmacists. Standard 1 on person centred-care of the standards for pharmacy professionals states that everyone has the right to be treated with fairness, dignity and respect and this includes respect for a person’s religion or belief, and respect for the rights of others.

2.11 All Pharmacy professionals, including independent prescribers, need to be aware of, and sensitive to, the many different needs and perspectives of patients. They need to be aware that individual patient reactions to clinical situations can be influenced by their religion or belief, or cultural and social factors, as well as clinical factors.

Pharmacist independent prescriber data

GPhC Commissioned surveys and reports

2.12 We commissioned several pieces of research related to the education and training of members of the pharmacy team over the past six years. Some of them, even if it was not their initial focus, entail information on prescribing education and practice. To inform this EIA , we used data from the following reports:

- [GPhC Registrant survey 2013](#)¹⁰
- [Prescribers Survey Report \(2016\)](#)¹¹
- [GPhC Register Analysis 2011 \(Pharmacists\)](#)¹²

2.13 The findings of this research are presented alongside our register data (next section) for more clarity

⁹ The Pharmacy Order 2010, Article 6(1)

¹⁰ [The GPhC Registrant survey \(2013\)](#)

¹¹ [Prescribers Survey Report \(2016\)](#)

¹² [GPhC Register Analysis \(2011\)](#)

and ease of comparison.

2.14 Separate research was conducted in relation to the education and training of future pharmacists. One report conducted in 2016 on trying to understand why Black-African candidates who undertake the registration assessment were doing less well than their peers from other ethnic background is particularly interesting in regard to equality and diversity¹³. Although it focused on pharmacist students and trainees, there are useful parallels to pharmacists undertaking an independent prescribing programme.

2.15 The above mentioned pieces of research were considered during the drafting process for the standards and we sought to ensure that a broad range of groups represented throughout our consultation and engagement process.

General Pharmaceutical Council (GPhC) register data: characteristics of pharmacist independent prescriber in Great Britain

2.16 The information on our register enables us to understand the demographic make-up of the current pharmacist independent prescriber group. On 4 January 2018, there were 6,015 annotated independent prescribers, including those pharmacists with dual independent and supplementary prescribing annotations (958). There were 359 annotated supplementary prescribers.

2.17 Since 2010, the general number of annotated pharmacist independent prescribers has steadily increased from 1,545 in 2010 to 6,015 in 2017¹⁴. In part, this is due to the relative decline in the number of supplementary prescribers, 1,431 in 2011 to 359 in 2017, as all accredited courses for supplementary prescribers ran out at the end of 2009¹⁵. As it was no longer possible to train as a supplementary prescriber, pharmacists would have trained as independent prescribers instead, or applied for a conversion course to become independent prescribers. As such, the number of pharmacists annotated as both supplementary and independent prescriber has remained relatively stable between 2011 and 2017.

2.18 There are limits to the data we currently collect on sexual orientation, gender reassignment, marriage/civil partnership, pregnancy/maternity. As a result, we recently modified our Equalities Monitoring Form to collect further protected characteristics data from pharmacist independent prescribers registering with us to address this gap.

Age

2.19 The majority of the pharmacist independent prescribers are aged between 30 and 39 years old (52 per cent) and a third of the pharmacist independent prescribers are between 40 and 54 (33 per cent)¹⁶.

| Age | Number | Percentage |
|----------------|--------|------------|
| 20 to 24 years | 0 | 0% |

¹³ [Qualitative research into registration assessment performance among Black-African candidates: Report to the GPhC 2016](#)

¹⁴ GPhC Register analysis, 2011 and 2017 CRM data

¹⁵ GPhC Register analysis, 2011

¹⁶ We also have protected characteristic data for supplementary prescribers but are focusing on independent prescribers in this EIA as we are no longer accrediting supplementary prescribing courses.

| | | |
|----------------|-------|------|
| 25 to 29 years | 528 | 9% |
| 30 to 34 years | 1,294 | 22% |
| 35 to 39 years | 1,411 | 23% |
| 40 to 44 years | 987 | 16% |
| 45 to 49 years | 749 | 12% |
| 50 to 54 years | 574 | 10% |
| 55 to 59 years | 302 | 5% |
| 60 to 64 years | 145 | 2% |
| 65 + | 25 | 0% |
| Total | 6,015 | 100% |

2.20 The age categories of PIPs have also seen a slight change between 2011 and 2017. In 2011, the vast majority of PIPs were in the age group 30-49 (78.1 per cent). In 2017, the most predominant age group for PIPs was 30-39 which accounted for 45 per cent of annotated PIPs. However, this was followed by the age group 40-49 with 15 per cent and the age group 50-59 with 15 per cent with the under 30, age group which accounting for 9 per cent.

2.21 A trend we received about during our pre-consultation engagement from course providers was that they are receiving greater number of applicants from more recent graduates, as opposed to previously where it was predominantly more mature and experienced registrants. As the data available the various age groups varies, it is difficult to ascertain if there has been a significant change in the non-dominant age groups.

Disability

2.22 27 per cent of pharmacist independent prescribers state they do not have a disability but 77 percent did not respond to this question, which makes this statistic much less reliable.

2.23

| Disability | Number | Percentage |
|--------------|--------|------------|
| No | 1,391 | 23% |
| Yes | 9 | 0% |
| Not recorded | 4,615 | 77% |
| Total | 6,015 | 100% |

Ethnicity

2.24 The vast majority of pharmacist independent prescribers (59 per cent) described themselves as 'White' and 23 per cent as 'Asian'. Only four per cent of pharmacist independent prescribers described themselves as 'Black'.

| Ethnicity | Number | Percentage |
|---------------------|--------|------------|
| Asian - Indian | 828 | 14% |
| Asian - Bangladeshi | 46 | 1% |
| Asian - Pakistani | 386 | 6% |
| Asian - Other | 128 | 2% |
| Black - African | 215 | 4% |

| | | |
|---------------------------|-------|------|
| Black - Caribbean | 15 | 0% |
| Black - Other | 9 | 0% |
| Chinese | 146 | 2% |
| White - British | 3,207 | 53% |
| White - Irish | 123 | 2% |
| White - Other | 219 | 4% |
| White and Asian | 21 | 0% |
| White and Black African | 6 | 0% |
| White and Black Caribbean | 6 | 0% |
| Other Ethnic Group | 116 | 2% |
| Other Mixed | 26 | 0% |
| Not recorded | 102 | 2% |
| Total | 6,015 | 100% |

2.25 It is difficult to compare data on trends in the ethnicity of PIPs, as the categories vary in different data sets, and some data sets are incomplete due to the self-declaring basis on which ethnicity data is collected on the register. However, there appears to be a greater diversification of PIPs between 2011 and 2017¹⁷. In 2011, the vast majority of PIPs identified as White British, White Irish or White other accounting for 80.1 per cent¹⁸. In 2017, there appears to be an increase in PIPs from other ethnic backgrounds such as Indian (14 per cent), Pakistani (6 per cent), Black African (4 per cent)¹⁹.

2.26 Although the majority of PIPs who did declare their ethnicity is White British, White Irish or White other (59 per cent combined), this is significantly less than previous data sets show. However, as mentioned, this data is to be considered with caution, due to a number of variables that prevent it from being complete or easily comparable across years.

2.27 Research undertaken on pharmacist education and training showed that some Black-African students experienced difficulties in forming productive study groups or supportive peer networks with students from other ethnic backgrounds and sometimes felt of isolated and excluded²⁰. This research also identified that there was a perceived lack of Black-African role models within the pharmacist education and training pathway to guide, inspire and motivate students of a similar background²¹. Even if not focusing on pharmacists training as independent prescribers, the findings from this research should make us reflect on pharmacist independent prescribers' training as some trainees might be experiencing the same issues.

Sex

¹⁷ GPhC Register analysis, 2011 and 2017 CRM data

¹⁸ GPhC Register analysis, 2011

¹⁹ 2017 CRM data

²⁰ [Qualitative research into registration assessment performance among Black-African candidates: Report to the GPhC 2016](#)

²¹ [Qualitative research into registration assessment performance among Black-African candidates: Report to the GPhC 2016](#)

2.28 The gender breakdown of pharmacist independent prescribers has remained quite stable between 2011 and 2017. In 2011, PIPs were 69 per cent female, whereas in 2017, this reduced slightly to 68 percent, whereas during the time period, male PIPs increased slightly from 31 per cent to 32 per cent²².

2.29 Two third of the pharmacist independent prescribers (68 per cent) are women.

| Sex | Number | Percentage |
|--------|--------|------------|
| Female | 4,065 | 68 |
| Male | 1,950 | 32 |
| Total | 6,015 | 100% |

Religion

2.30 As for the data pertaining to religion, we recorded the religion of so few pharmacist independent prescribers that it makes little sense to draw conclusions from the data we have on religion. 80 per cent of the pharmacist independent prescribers on our register did not respond to this question. From the 23 per cent that did provide their religion, seven per cent identify as Christians, five per cent as Muslim and four per cent stated they did not have a religion.

| Religion | Number | Percentage |
|--------------|--------|------------|
| Buddhist | 8 | 0 |
| Christian | 443 | 7 |
| Hindu | 125 | 2 |
| Jewish | 1 | 0 |
| Muslim | 299 | 5 |
| Sikh | 45 | 1 |
| None | 229 | 4 |
| Other | 25 | 0 |
| Not recorded | 4,840 | 80 |
| Total | 6,015 | 100% |

3. Screening for relevance to equality and diversity issues

| Does this project/policy have significant/disproportionate? relevance to | Yes | No |
|--|-----|----|
| Age | | ✓ |
| Disability | | ✓ |
| Gender reassignment | | ✓ |

²² GPhC Register analysis, 2011

| | | |
|--------------------------------|--|---|
| Marriage and civil partnership | | ✓ |
| Pregnancy and maternity | | ✓ |
| Race | | ✓ |
| Religion or belief | | ✓ |
| Sex | | ✓ |
| Sexual orientation | | ✓ |

4. From the answers supplied, decide what further work needs to be undertaken if the proposals impacts upon diversity or equality issues

4.1 Yes, full EIA required.

4.2 We currently do have enough evidence to tick any of the categories in the screening table. However, evidence of impacts on protected characteristics might be brought up in the consultation.

5. Date and method of consultation

Pre-consultation engagement

5.1 We used a range of communication activities prior to drafting the standards and consulting on them to maximise participation across a diverse range of stakeholder groups. We also used general and targeted engagement approaches to reach relevant audiences. Below is a summary of our pre-consultation engagement activity:

- Discussion paper consultation launched in November 2017
- Targeted emails to stakeholders, which included public and patient representative organisations
- Articles in our online blog 'Regulate'
- Members of staff on hand to answer any questions throughout the discussion paper consultation process
- Meetings with IP providers in London, Belfast and Newcastle
- Meetings with schools for pharmacy from September to November 2017
- Engagement with IP expert advisory panel to confirm finalised version of the standards and learning outcomes

5.2 The objectives of the pre-consultation engagement were to understand what independent prescribing providers and schools of pharmacy think of current independent prescribing education and training requirements in regard to the needs of future roles. We also discussed entry requirements and extending the supervision of pharmacists in practice to other independent prescribers.

5.3 As part of the discussion document survey, we have included a question about equality and diversity (Question 16: "Are there any equality, diversity or inclusion issues you think have been raised by our

proposals?”) to ensure that we captured any issues that respondents wish to raise. We analysed the responses provided by stakeholders to Question 16 of the survey.

5.4 In total, we received 577 responses. Form these:

- 526 respondents (91 per cent) did not think there was anything in the standards or suggested changes to the criteria for registration that disproportionately affected any particular group over others.
- 11 respondents (two per cent) did not comment that question.
- 40 respondents (seven per cent) felt that our proposed changes would disproportionately affect particular groups over others.

5.5 Only five respondents raised EDI issues. Their comments focused on:

- The need to have a strong focus on equality and diversity in the standards
- The need for monitoring equality and diversity issues of both pharmacists and supervisors
- The extension of supervision to other independent prescribers than DMPs maybe improving equality and inclusion as non-medical supervisors might be more likely to be women and from under-represented groups.

5.6 No issues were raised in relation to any of the protected characteristics during stakeholder engagement. However, it was agreed during the drafting of the standards that there was a greater need for further emphasis on equality and diversity within the standards. Therefore, the draft standards emphasise that equality and diversity data should be used actively to inform course design and delivery and trainees' experience (Domain 2).

5.7 The findings of this work will be presented to the IP expert advisory group on 15 January 2018 and the projected impact of the proposals were considered as part of the drafting and pre-consultation process.

Formal consultation and focus group

5.8 To be completed after consultation.

6. Give a brief summary of the results of the consultation / involvement. How have these affected the proposal?

- 6.1 Please refer to our analysis of discussion paper responses and stakeholder engagement meetings for details of the outcomes²³.
- 6.2 All issues relating to equality and diversity identified through the engagement and consultation process have been set out in detail in Section 7 below.

7. Full impact assessment

Explain the potential impact (whether intended or unintended, positive or adverse) of the proposal on individual groups on account of:

Age – consider impact on people of different ages such as young or old.

- 7.1 We do not have evidence to suggest any disproportionate impact of the proposals in relation to age.

Trends in the age profile of pharmacist independent prescribers

- 7.2 Different age groups have distinct healthcare and education needs and concerns. As part of our research and engagement activity, we have sought to assess the impact of our proposals on people of different ages.
- 7.3 The majority of the pharmacist independent prescribers are aged between 30 and 39 years old (45 per cent) and a 29 percent of the pharmacist independent prescribers are between 40 and 54.
- 7.4 As the age of pharmacists undertaking independent prescribing education and training is spread across a wide range, it is important that education and training is sufficiently flexible to allow trainees to fit in with their work, family and other commitments and our standards emphasise this.
- 7.5 Equality and diversity is embedded in the standards, and occupies a separate domain in part 2 of the standards to ensure course developers and providers give due consideration to these facts and data in course design and delivery. To support this, the evidence framework will also provide further information about how equality and diversity must be embedded in course design and delivery.
- 7.6 In monitoring the impact of the standards, our accreditation, recognition and quality assurance processes requires awarding bodies and course providers to provide evidence to demonstrate how they apply and meet our standards.

²³ Supervising pharmacist independent prescribers in training: Summary of responses to the discussion paper and Standards for the education and training of pharmacist independent prescribers, Summary of findings: independent prescriber pre-consultation engagement.

| |
|--|
| <p>Impact of the proposal to remove the two-year work experience requirement</p> <p>7.7 Removing the two year requirement might have an impact on the age of pharmacists undertaking independent prescribing education and training but this will be left to the discretion of education providers.</p> |
| <p>Disability – consider environmental, social and attitudinal barriers</p> |
| <p>7.8 We do not have evidence to suggest any disproportionate impact of the proposals in relation to disability.</p> |
| <p>Gender reassignment – consider impact on transsexual and transgender people including bullying, harassment and discrimination issues not least ensuring privacy of data to avoid disclosure of gender history</p> |
| <p>7.9 We do not have evidence to suggest any disproportionate impact of the proposals in relation to gender reassignment.</p> |
| <p>Marriage or Civil Partnership – consider impact on married people or people in a civil partnership , young or old</p> |
| <p>7.10 We do not have evidence to suggest any disproportionate impact of the proposals in relation to marriage or civil partnership.</p> |
| <p>Pregnancy or maternity – consider impact on pregnant women and those on maternity leave</p> |
| <p>7.11 We do not have evidence to suggest any disproportionate impact of the proposals in relation to pregnancy or maternity.</p> |
| <p>Race – consider impact on people of different ethnic groups, nationalities, gypsies, travellers, languages etc.</p> |
| <p>7.12 We do not have evidence to suggest any disproportionate impact of the proposals in relation to race.</p> |
| <p>Religion or belief – consider impact on people with different religions or beliefs, or none</p> |
| <p>7.13 We do not have evidence to suggest any disproportionate impact of the proposals in relation to religion or belief.</p> |
| <p>Sex – consider impact on men and women; working arrangements, for example, part-time, shift working, caring responsibilities</p> |
| <p>7.14 We do not have evidence to suggest any disproportionate impact of the proposals in relation to sex.</p> |
| <p>Sexual Orientation – consider impact on bisexual, gay, heterosexual or lesbian</p> |

7.15 We do not have evidence to suggest any disproportionate impact of the proposals in relation to sexual orientation.

Other diversity and equalities related issues

7.16 No other issues identified.

10. Welsh Language Scheme

10.1 A Welsh version of all standards, discussion paper and consultation documents will be provided. This will ensure that Welsh speaking stakeholders have the opportunity to provide input.

10.2 We will also provide a Welsh version of finalised standards and guidance.

11. Monitoring

How will the implementation of the proposal be monitored and by whom?

11.1 This analysis is intended to assist Council in considering whether the changes to the standards should be approved and/or subject to further amendment before introduction.

11.2 Once the standards have been agreed, courses will be written based on the new standards and learning outcomes.

11.3 Our accreditation, recognition and quality assurance processes allow us to monitor and assess courses, to ensure they meet our standards. Through the upcoming review of accreditation and quality assurance, we will consider how feedback is incorporated into evidence gathering and ensure we have appropriate mechanisms in place to monitor our mitigation strategies and are aware of any other equality concerns that emerge.

How will the results of monitoring be used to develop this proposal and its practices?

11.4 The results from the discussion paper and stakeholder engagement have informed the draft standards, which we also consulted upon.

What is the timetable for monitoring, with dates?

11.5 The standards will be kept under continuous review, with a formal review carried out every 3 – 5 years by the Education team.

Meeting paper

Council meeting on Thursday, 08 February 2018

Public business

Promoting professionalism, reforming regulation

Purpose

To provide the Council with the GPhC response to the reforming regulation, promoting professionalism consultation.

Recommendations

The council is asked to note this paper.

1. Introduction

- 1.1. On 31 October 2017, the four UK governments launched a consultation seeking views on proposals to reform the system of regulation for healthcare professionals in the UK. The consultation closed on 23 January 2018. It sought views on what is needed to protect the public and at the same time support the development of the workforce.
- 1.2. The responses to the consultation would allow the government to consider future options for the development of regulation of healthcare professionals in the UK.
- 1.3. The consultation provided an opportunity to discuss the purpose of professional regulation, and the role of regulators in the improvement of quality as well as assurance.
- 1.4. The consultation sought views on a number of areas, including:
 - Assessment of which healthcare professionals are regulated and the level of regulatory oversight required;
 - The number of regulatory bodies and the role of Professional Standards Authority;
 - Fitness to Practise, in particular views on mediation and ensuring that all the regulatory bodies have the full range of powers for resolving FTP cases;
 - Whether the regulators have a role in supporting professionalism, and how this can be done

- Opportunities for the healthcare professional regulators to work together more effectively in the future, for example through shared services, adjudication and common standards; and
- Autonomy of regulators and accountability to governments across the four countries.

1.5 The GPhC response to the consultation can be found in Appendix 1.

2. Our approach to responding to the consultation

2.1 The GPhC developed a narrative approach to the consultation, and used the strategic plan to underpin our response. In addition, we answered the questions directly, where appropriate.

2.2 In developing our response we collaborated with the other regulatory bodies to identify areas of synergy and commonality.

2.3 Whilst the focus of the consultation was professional regulation, we raised awareness of our unique role as both the regulator of pharmacy professionals and also registered pharmacies, and used our response as an opportunity to highlight the significance of our dual role for patients and the public.

2.4 The following principles, which we discussed by Council in Dec 2017, were used to inform the development of our response. These were:

- Demonstrate leadership across regulation and provide the context of pharmacy ;
- Take the opportunity to think about the role of healthcare regulation in the long term and in the context of the development of health and care services a number of years from now;
- Be clear about what we think is achievable and what we would like from the consultation;
- Demonstrate our commitment to assurance, improvement and support of pharmacy (and more broadly health and care);
- Challenge the assumptions about effective regulation using the evidence drawn from our role regulating people and places;
- Draw attention to the steps we have already made to deliver reform with and without legislative change.

3 Equality and diversity implications

- 3.1 The consultation sought views on a number of broad areas but did not set out concrete proposals for reform of health professional regulation in the future. Therefore we did not provide the requested data.
- 3.2 A range of potential outcomes were presented for which information is requested on potential impact. Owing to the fact not one single proposal was made in the consultation, we were unable to identify and furnish information on the opportunities to enhance or the risks to diversity and inclusion. As proposals become clearer, we will continue to provide information both to Council and as part of any further discussions or consultations with the governments.

4 Communications

- 4.1 This was a Department of Health consultation and therefore they were the lead organisation for communicating and raising awareness of the consultation. We raised awareness of the DH consultation through an article in the December edition of Regulate and through posts on our social media accounts. We are also encouraged organisations we have worked with which represent patients and the public to respond directly to the consultation, so that the views of the people they represent could be heard.
- 4.2 We also raised awareness of the consultation with GPhC staff and involved staff, partners and associates in developing the response.

5 Resource implications

- 5.1 The resources required to respond to this consultation were planned for in business planning for 2017/18.
- 5.2 Any future changes to the regulation of healthcare professionals could have resource implications for the GPhC; however at this stage these are unknown.

6 Risk implications

- 6.1 Failure to effectively engage with the consultation could result in future proposals that do not take account of the Council's views on the purpose of professional regulation, and the valuable contribution that can be made to improving quality.

- 6.2 There may be a range of risks and opportunities presented by the process of reform, but the consultation document did not set out proposals upon which an analysis can be made. Further risk analysis will be conducted if and when the next steps become clear.

7 Monitoring and review

- 7.1 Once the consultation has closed, the Department of Health will produce a summary of responses. We will actively monitor this, and seek opportunities to collaborate with the other healthcare regulators and the Department of Health.

Recommendations

The council is asked to note this paper.

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23 February 2018

GPhC response to DH consultation: *Promoting professionalism, reforming regulation*

1. Foreword

There is, and will continue to be, a lot of change ahead across the health and care sector. This requires all healthcare professionals, and the environments in which they work, to be flexible and focussed on the patients and public to whom they provide advice, support and treatment. In this context, we believe that a few things will not change. The first of these is that patients and the public will always have the right to expect safe and effective care from healthcare professionals. The second is that the attitudes and behaviours of healthcare professionals in their day-to-day work make a key contribution to patient safety and the quality of care. Finally, that the system and environment in which healthcare is delivered should be optimally designed and governed and act as enablers for professionals to deliver good quality care.

We welcome the consultation ‘Promoting professionalism, reforming regulation’, and the objectives it is seeking to achieve. At the heart of our strategy are the key objectives we want to achieve for patients and the public: ‘assurance’ and ‘improvement’. We have long said that regulation must be more than enshrining and enforcing minimum standards. Our focus should be on promoting and supporting professionalism because it enhances patient safety and quality of care. The consultation reflects this view and is an opportunity to enhance the tools we have available to achieve these goals.

We also believe that a longer term vision for healthcare regulation is needed. Changes in society, technology and innovation will alter the way that healthcare is delivered, and the way that healthcare professionals provide services. Whilst it is hard to predict the future, we can be sure that people’s health and care needs will continue to evolve and change and therefore so must the services to which they have access, and how they then access them. To meet those challenges we as regulators must also evolve.

The purpose of regulation must be clear and consistent, and its design must provide autonomy and flexibility as well as accountability. Our legal framework must serve that purpose so that we are equipped to regulate effectively, and we should be held to account for doing so. It is only then that we can assure the delivery of a pharmacy workforce, pharmacy premises and services that are fit for the future, providing safe and effective care to patients and the public.

2. About the GPhC

We regulate pharmacists, pharmacy technicians and pharmacies in Great Britain. We work to assure and continually improve standards of care for people using pharmacy services, by:

- Setting standards for pharmacy professionals and pharmacies to enter and remain on our register.
- Seeking assurance that pharmacy professionals and pharmacies continue to meet our standards, including by inspecting pharmacies.
- Acting to protect the public and to uphold public confidence in pharmacy if there are concerns about a pharmacy professional or pharmacy on our register.
- Helping to promote professionalism, supporting continuous improvement and assuring the quality and safety of pharmacy.

3. Introduction

3.1 Regulation of pharmacists, pharmacy technicians and registered pharmacies transferred to the GPhC in 2010, and therefore our legislation is relatively new compared to the other regulators. We have seen the benefits of this in that our legislation is not as prescriptive or cumbersome as older versions, and therefore we have benefitted from being able to regulate in a more flexible way. At the same time we have also seen how, in a short period of time, our legislation could be improved as the pharmacy landscape and that of the health and care environment change at a rapid rate.

3.2 Our Council has made clear in its strategy what we want to achieve for patients and the public.

'Firstly, we want to provide assurance to patients and the public about the standards of practice and quality of services they will receive from pharmacy professionals and pharmacies, now and in the future. Secondly, we want to play our part in improving the quality of pharmacy practice – so that patients and the public can receive better care and advice, which will in turn improve their health and wellbeing.'

3.3 Regulation is most effective at ensuring safe and effective care for people who use pharmacy services when it has a wide range of flexible regulatory tools that can be used to provide assurance and help to promote improvement, which reduces the risks of poor care in the future. This means we require a legal framework that provides us with the flexibility to regulate in a changing context, recognising the role of technology and innovation and the changing needs of a population that becomes ever more diverse and informed. This framework could be delivered through one or more section 60 orders, and would not require a Bill.

3.4 Flexibility must be balanced with clear arrangements for accountability. In order to hold the confidence of the public and professions, we must ourselves be open to the same principles of giving assurance and driving improvement through effective oversight of what we do and how we do it. The consultation offers many options for how we may assure and improve both pharmacy and ourselves in new ways. We are open to these options; in fact we have proposed many of them over the course of the years of discussion on reform. Regulatory models should be designed to serve a clear purpose. It follows that:

- The people and places that are regulated must be the right ones to provide safe and effective care
- The regulatory model must suit that system of care.
- The oversight of the regulatory model must be focused on the right things.

- 3.5 If this is the case, then the entire system of care, regulation and public accountability will be able to drive both assurance and improvement. The wrong choices now will have adverse consequences over many years ahead.

4. Protecting the public

Deciding which professional groups are subject to regulation

- 4.1 Health and social care has changed considerably in recent years with new services, new technology, and new roles developing to meet the changing needs of the population; and it will continue to change. It is therefore essential that regulation should be flexible or it risks embedding approaches which become redundant or outdated in the future. That may mean that new professions need regulation or that, as new roles emerge, some professions will no longer require regulation. The form of that regulation must also develop over time.
- 4.2 It is for governments to determine which professions should be regulated and how they should be regulated. In making these decisions, we believe there are some important tests that need to be met and the rationale for decisions should be clear and transparent. These are:
- Regulation should serve the public interest and therefore members of the public, and particularly patients, must be involved in the decisions.
 - Sound regulation is only effective with the consent of the regulated and so aspirant or regulated groups must be involved in decisions.
 - Any model for regulation should support professionalism and improvement beyond minimum standards.
 - Regulation should enable safe multidisciplinary working and avoid reinforcing the segregation of professional boundaries.
 - Given the way in which the PSA and regulators are funded, there could be a perceived conflict of interest, and the government must be mindful of this when seeking advice about which groups are subject to regulation.
 - The competing priority of ensuring a suitable health and care workforce needs to be balanced against appropriate regulation to ensure the quality of a workforce that delivers care safely.
 - The process for making decisions, and the decisions themselves, should be robust and transparent.
 - For any decisions on de-regulation, consideration should be given not just to current roles but possible future roles to avoid short-sighted decisions.
 - The impact of de-regulation on a professional group should be considered. The presence of a regulatory body may mean that other organisations, such as professional bodies, are not

resourced to provide the services of a regulator. This may lead to negative unintended consequences for professional groups subject to de-regulation and the people to whom they provide services.

- 4.3 The criteria proposed for decision-making require further thought and development in collaboration with regulators and others, for example patient and public representative organisations, professional leadership bodies and the regulated professionals themselves.
- 4.4 The proposed model for assessing whether professional groups should be regulated does not take account of the diversity of practice within and across professional groups in the evolving health and care system. For example, whilst the majority of pharmacy professionals work in patient facing roles (within community pharmacies or in hospitals providing care to large numbers of patients and the members of the public on a day to day basis), many work within other areas of practice, such as industry, academia and research (where perhaps there is less patient contact, but their attitudes and behaviours will have an impact on the safe and effective care that people receive). There is a risk that a professional group might be regulated because a small number perform a 'high risk' activity or are un-regulated because the majority performs a 'low-risk' activity. The amount of contact a professional has with patients and the public should not equate to a presumed 'level of risk'. We have learnt from previous failures within the NHS that professionals who have relatively little contact with patients, but who have senior roles within hospitals and trusts can have a significant impact on the safe and effective care that people receive.
- 4.5 Nor do the proposals take account of changes to the way in which professional groups may practise in the future. For example within pharmacy practice, advancements in technology have meant that services are increasingly being provided at a distance, and with this come additional risks that need to be mitigated. Equally, the use of robotics within the dispensing service when properly applied can mitigate some of the risks around human error. These kinds of innovations demonstrate that a 'risk' profile does not remain static or measurable at one particular point in time and underline further the need for any changes to the regulatory regime to be flexible in practice.
- 4.6 When statutory regulation or accredited voluntary registers are not appropriate for groups, there would be advantages to the use of prohibition orders. We would support prohibition orders because it is right to consider not only traditionally defined professionals but also unregistered staff and their impact on the delivery care. We also believe it is a sound method to have a full range of options available when making decisions on how to protect the public.
- 4.7 We draw parallels here to our work on establishing disqualification procedures for pharmacy owners. We have not been able to use our disqualification powers in relation to registered pharmacies because the relevant legislation is very narrowly and prescriptively drafted. We have seen that this can undermine confidence, through misunderstanding of the powers we hold and

the tests that must be applied. A pharmacy defence organisation has called for a review of our powers, and we believe a legitimate debate should be had.

- 4.8 If prohibition orders and negative registration were to be taken forward, further consideration will need to be given to ensure that the legal framework is sufficiently flexible, and proportionate to be used effectively to protect the public. In addition the practicalities of such a list, for example who administers the list and how decisions are made would need to be considered. Again, further collaboration with patients and the public and others will be necessary.

Number of regulatory bodies

- 4.9 Regulation of health professionals has developed alongside the professional groups for the most part. This has meant that professional groups have different regulators and differing models of regulation because they were developed at different times. This has resulted in significant variations in the ways in which regulators can address the same, or similar issues and also complexity for those who are dependent on regulation. However, it does also have advantages, not least of which is that the regulators have an understanding of the context of the professional groups they regulate. This is particularly the case for pharmacy as we regulate registered pharmacies as well as pharmacy professionals.
- 4.10 The future number and configuration of regulators is a decision for the Governments. However, we believe there are a number of tests that should be used to support any decision to make changes to the current system. These are:
- There should be clear benefits to patients and members of the public to making any change that demonstrably provides greater benefit than the inevitable distraction placed on professionals subject to any change.
 - The regulators in whatever number or configuration should be well understood by the public and they should be accessible. The rationale for any change must be driven by the needs of the public and the professional context rather than by an academic algorithm.
 - The cost implications of reducing or reconfiguring the number of regulatory bodies needs to be set out clearly and weighed against the benefits for patient safety and accessibility.
 - They should have the necessary powers and resources to discharge their functions to assure, improve and support professionalism on behalf of members of the public.
 - The contextual understanding of professions, where and how they work must not be lost. The recent decision to create a regulator for social workers in England demonstrates the importance of a regulator that understands a profession and the context in which its members work.

- 4.11 We reject the notion of “a high street regulator”, which has sometimes been proposed as an option for merger, as it is not reflective of the many ways in which patients, the public and carers access healthcare services. If the definition of ‘high street healthcare’ means services available to the public in retail settings, that is in itself quite restrictive, and does not reflect ways in which access may occur. For example, within the context of pharmacy, services will be increasingly delivered online (both as clinical consultations and the dispensing of medicines), and delivered directly to a patient’s home, as well as a variety of other settings not on the high street , such as care homes.

The role of the PSA

- 4.12 We have no strong opinions on the future role of the PSA. We urge the Governments to focus on the purpose of professional regulation, and the framework that that implies. The level of oversight and accountabilities of the regulators should follow once there is this clarity.
- 4.13 The future role of the PSA should demonstrably provide additional benefits and protection for patients and the public beyond that provided individually and collaboratively by regulators.

5. Responsive regulation

- 5.1 We welcome the recognition that regulators require more flexibility to adapt to new ways of working. In pharmacy regulation, we have moved away from setting minimum standards, and from a prescriptive approach to those standards. We recognise that pharmacy professionals are exactly that; professionals who must exercise judgement and ensure that person-centred care is delivered wherever they practise. Our standards for both pharmacy professionals and registered pharmacies focus on the outcomes that patients and the public have a right to expect and we seek assurance that those outcomes are being met using the regulatory levers that we have, for example educational outcomes, revalidation, registration, fitness to practise procedures and inspection. We ask governments to be clear about the purpose of regulation and the outcomes that they expect regulators to achieve, and then provide us, and others, with a legal framework that enables and empowers us to regulate in a proportionate, flexible way to achieve those outcomes.
- 5.2 We agree that all regulators should have the same tools at their disposal for managing and responding to concerns. Regulators should also be able to use other approaches for managing concerns as they consider appropriate for ensuring safe and effective care. For example, the regulators should be given the flexibility to develop alternative mechanisms for managing concerns that fall outside the current tools we use, whether that is mediation or something else. Otherwise there is a risk that we are unable respond in a flexible manner as the types of

concerns we receive change over time. A legal framework that provides us with the flexibility to design additional tools through rules and regulations would be welcome.

- 5.3 Fitness to practise currently can feel like an adversarial process, invariably causing anxiety and fear for those involved. Instead of focusing on the needs of patients, professionals are concerned about 'what the regulator will say or do'. Fitness to practise processes should be focused on the most serious types of concerns, and we believe that there should be further opportunity to look at the purpose of fitness to practise, not just the mechanisms for dealing with concerns. We can then use our other regulatory levers, such as revalidation, inspection and registration to support and promote professionalism with the aim of improving the quality and safety of the care that people receive.
- 5.4 We believe that much that can be done without new legislation; for example our revalidation model has been designed, piloted and consulted on without the need for additional rules and regulations. It will be implemented in 2018, and has been widely welcomed by the pharmacy sector. We are also developing guidance for pharmacy owners about supporting and empowering the whole pharmacy team. Our role as the regulator of registered pharmacies provides us with the opportunity to ensure that the environment in which pharmacy services are delivered supports and enables the delivery of safe and effective care.

Supporting professionalism

- 5.5 The consultation raises important questions about the role of regulation in supporting and promoting professionalism. We believe the professional knowledge, attitudes and behaviours of the people working in pharmacy offer the best assurance to people using pharmacy services. Our most effective role is in helping to promote an environment in which professionalism can flourish. We strongly agree that regulators have a role in supporting professionalism.
- 5.6 Our standards for pharmacy professionals are outcome focused. They support and promote professionalism, making clear the expectations of patients and members of the public. The standards are not prescriptive but explain the attitudes and behaviours that pharmacy professionals must demonstrate. We have been aware that we must reflect what we say about our expectations of professionalism through all our work, for example when we manage concerns.
- 5.7 We have already made changes to the way we regulate pharmacy professionals and registered pharmacies to play a more effective role in supporting professionalism and we are working now to do more:

- Our standards for pharmacy professionals, developed collaboratively with patients and pharmacy professionals came into effect in May 2017. These standards set the common expectations for person-centred professionalism as nine outcomes applicable to the full range of roles and settings of pharmacy practice. This approach was welcomed by patients and the public, as well as those we regulate, during the consultation. We also heard from some that the standards we had developed could equally apply to other healthcare professionals. We also recognise that the development of standards is not the end of our regulatory role. We have a clear responsibility to communicate these to pharmacy professionals, patients, employers and others on an ongoing basis, so that the standards are understood and applied in practice.
- Our approach to revalidation, again co-created with pharmacy professionals and taking into account the expectations and views of members of the public and patient representatives, is designed to encourage reflection upon those professional standards and on the benefits to the people using a pharmacy professional's services. Our revalidation model demonstrates what we have achieved without legislative changes in the context of the evolving profession.
- Through inspection of registered pharmacies, we seek assurance that our standards are being met and require the development of improvement action plans in those circumstances that standards are not met. We provide pharmacy owners with inspection reports which can be used by owners to improve the quality of services they provide. We will also begin to publish inspection reports once the necessary legal power is commenced.
- We are now turning our attention to the initial education and training of pharmacy professionals to ensure that our standards are woven into training, alongside the skills to reflect upon learning and practice to drive improvement and foster ongoing assurance.

- 5.8 As well as focusing on professionalism, we have also acted in our role as the regulator for registered pharmacies to ensure that the ways that people employ and deploy pharmacy professionals are supportive of professionalism. There is undoubtedly interplay between the setting of practice and the people in it which can have a significant impact on both professional behaviours and the experience and outcomes for patients.
- 5.9 We believe that professionalism can be further supported by regulators through:
- Engaging further with patients, the public and their representatives to understand their current and changing expectations of care, in particular the common standards and approaches they expect from all health professionals.
 - Communicating the expectations placed on professionals through supportive methods designed to assist adaptation in the context of change, such as sharing learning we gather from the concerns we hear from members of the public digitally
 - Working more regularly and collaboratively alongside the organisations that employ, fund and support professionals.

6. Efficient regulation

6.1 Working more closely together is undoubtedly a way in which the regulators can drive both greater efficiencies and effectiveness and has not required legislative change. Healthcare professionals already work alongside one another and increasingly do so as health and social care become further integrated, for example through the work of the sustainability and transformation plans in England. Similarly, so too must the regulators, especially as distributed multi-disciplinary team working becomes more common and patients and the public will less easily recognise the boundaries between professions simply based on where people work and what people do. It is also notable that members of the public often will not recognise or indeed be interested in the differences between regulators. Many may see the role of professional and systems regulators as essentially being the same thing.

6.2 The purpose of regulators' collaboration needs to be clearly articulated so that it can be used as an appropriate test for evaluating efficiency and effectiveness. We believe the purpose of collaboration is to make the experience of engaging with regulatory bodies trusted, consistent, simple, and valued by members of the public, health professionals, their employers and any other party with a stake in regulation. Therefore, the focus on possible financial savings, which is likely to be a by-product with no guarantee that the benefit flows to patients, should not be a primary motivation or driver for that collaboration. Indeed it is at present unclear to us whether any projected savings would in fact materialise, or whether they would be significant enough to outweigh any disadvantages.

6.3 There are already many examples of effective co-operation between the health regulators but we agree and are keen to develop this further. We have, for example:

- Carried out joint inspections with other systems regulators, the Care Quality Commission and MHRA, when looking at services that cut across the GPhC and others; and
- Worked collaboratively with other professional regulators on areas such as conflicts of interest, the duty of candour and pandemic flu statements.

6.4 Mandating and requiring collaboration to be reported on through clear accountability processes could provide a useful opportunity for regulators to show how they are continuing to work together in the interests of patients and the public.

6.5 Often the barrier to effective collaboration is felt to be moving decisions through differing governing structures, and the scheduling of such collaboration when each regulator works to a different timetable. Whilst one solution could be to look at new legislation that mandates such collaboration, or changes to the governance structures of the organisations we believe that there are other more efficient, less costly mechanisms that can be adopted much more rapidly. For example, through effective agreements on how certain types of joint-working are governed and led.

6.6 We strongly believe that the principle of joint working should not be limited to the professional regulators. The environments in which health professionals work are critical to delivering the context for professional, safe and effective care. If the environments are not supportive of the professionals who work in them, then the individuals in that place (both professionals and patients) suffer. As the regulator of both pharmacy professionals and registered pharmacies we believe the interplay between the regulation of people and places is fundamental to assuring and improving health and social care.

6.7 It is a decision for government on whether structural change is needed to foster more effective collaboration between regulators but we think the tests of any decision should be:

- That the views of the public and of the professions are taken into account.
- That the understanding of the context of health professionals' practice should not be lost in any future arrangements.
- That the outcomes achieved are enhanced trust, consistency, simplicity and value for the people who are regulated or rely upon regulation.

Data driven regulation

6.8 Regulation has evolved from a system based on assumptions about the role and functions of regulatory bodies and the impact they have on regulated communities and the people they are designed to protect. This evolution has taken place as data and the insight it gives have grown from the work of all the regulators.

6.9 The power of data to inform regulation is great, but it is also necessary to be realistic about what can be achieved. It is unlikely, based on the evidence that we have, that regulators will be able to use data in such a way to intervene before harm occurs in a particular instance. However, we can use our data, especially when shared, to support professionalism, empowering the people and places we regulate to increasingly avoid the rare instances of harm and more widely improve the experience and outcomes of patients. There is also an opportunity for data driven regulation to provide us with a greater understanding of equality, diversity and inclusion issues and the effect of regulation on these.

6.10 We are committed to looking at how best we can share the data we hold and related insights across our functions, for example:

- Within fitness to practise, not only the learning from cases but also the information we hold about concerns that do not progress through the fitness to practise process.
- Through CPD returns and in the future revalidation.

- Uniquely through our work in regulating registered pharmacies and inspection - information and data we hold about meeting our standards, and the publication of inspection reports.
- 6.11 Data sharing might also assist with targeting our resources more effectively. For example, we may be able to see patterns about certain geographies, programmes of professional education or types of service which suggest that we should scrutinise areas using our tools for assuring standards more frequently or more intensely. This is something we are currently exploring in our role as the regulator for registered pharmacies and as a result of the introduction of revalidation for pharmacy professionals.

Autonomy and accountability

- 6.12 Regulation is most effective when it is independent from governments, flexible in the face of change, but accountable through a variety of transparent mechanisms. As we have said, we believe we need greater flexibility than we currently have because our legislation can sometimes be a barrier to our taking appropriate and timely action and seeking change can be a long process. Further, we suggest that we could provide such assurances to the parties to whom we are accountable, granted that additional flexibility. This would ensure there are checks and balances over our decisions and actions.
- 6.13 Firstly we would gladly offer consistent accountability to all legislatures on the breadth of our work. We welcome direct accountability to Parliament, the Scottish Parliament and the Welsh Assembly across the discharge of all of our functions to regulate pharmacists, pharmacy technicians and registered pharmacies.
- 6.14 Secondly we would suggest that there may be different mechanisms for us to be held to account, perhaps some collectively with other regulators, which we would want to explore so that our work is more visible and can be tested consistently by governments, the public and the professions.
- 6.15 Finally, the culture of autonomy and accountability should run like a strong thread through the entire system. Health professionals and regulators should all have the flexibility to innovate, change and respond to the needs of the people, but do that within a clear framework of accountability. This culture is the one that will empower the whole system to adapt and improve safely, in the face of change.

Governance

- 6.16 Our Council is constituted of seven pharmacy professionals and seven lay members, with a lay chair. The council directs the strategy of the organisation and holds the executive to account for its performance. This method of governance has proved very effective because there is:
- Separation between the council and the executive providing clear lines of accountability. Without that separation it is much more difficult for the executive to be held to account for their actions.
 - Balanced representation of the views of professionals and informed lay people.
- 6.17 Given the clear effectiveness of our current arrangements we will continue to value clear lines of accountability and a balance of professional and lay perspectives. The professional members are important and necessary members of the Council, who ensure that the context in which regulated professionals practice is understood, and whose presence on Council also enhances the confidence of the regulated professions in the deliberations and decisions made. It is for these reasons that a professional and lay Council is most valuable. When considering the number of Council members, it is important that the size is not so small that it precludes effective decision making and continues to ensure that the context of the regulated is considered. Decisions in the past have resulted in a reduction in the size of the Councils of regulatory bodies, and there is no doubt that this has improved governance overall; but the case for a further reduction is not made, in our view.
- 6.18 The breadth of the structure of our Council enables us to draw upon a wealth of experience of different models of governance, and we remain unconvinced of the potential benefits of a unitary board where the executive do not have any clear lines of accountability within the organisation. Such an arrangement compromises the accountability of the Chief Executive – who is then playing two roles of blurred identity, which have the potential to conflict.
- 6.19 The views of employers are critical to the way in which we regulate. Much of the regulatory model is dependent on employers understanding how we regulate and their responsibilities in relation to that. This is especially true in the context of pharmacy as we regulate registered pharmacies as well as the pharmacy professionals who work in them and in other settings. Employers within the pharmacy context include not only NHS organisations but also commercial organisations of varying size and purpose. We consider the important views of employers through a number of different methods, such as:
- Strategic relationship managers for very large employers.
 - Employer representatives on working groups such as that for revalidation.
 - Consultation and engagement activities.

- 6.20 We feel however that the interests of employers and those of the regulator and the regulated can sometimes not be aligned fully. The regulator has an important role in balancing the interests of the patients, of professionals and the economic realities of a commercial operation. Therefore, we do not agree that governing councils or boards should be mandated to be constituted to include employers. The existing legal duties to consult, including with employers, and the other methods of engagement seem more appropriate to include the views of employers in our decision-making but where necessary to take action in the interest of the public that may not be consistent with the interests of employers.
- 6.21 All regulators should have a clearly stated strategy and model for the assurance they provide that the people and places they regulate are safe and effective. We have been developing our approach in this area and see the range of levers we have available to us as working collectively to provide that assurance. From initial education and training, registration and renewal of registration, revalidation for pharmacy professionals, quality assurance of registered pharmacies, and to investigating and acting upon concerns, the whole model drives assurance and improvement.

Fees

- 6.22 The cost of regulation sits with the people and places that we regulate. This means that we are accountable not only to the Governments and the general public for the services we provide but also to pharmacy professionals and registered pharmacies to make sure we are performing those services as efficiently as possible.
- 6.23 We have already been working to make sure that we are both efficient and effective and that we evidence it. We were able, through a commitment to efficiency, to decrease fees for pharmacy professionals in 2011 and even after an increase in 2015, the cost remains lower than it was in 2010.
- 6.24 We agree therefore that if savings are realised, which do not need to be committed to further effective public protection or to support professionalism, then fee reductions would be appropriate. However, it is difficult based on the proposals in this consultation to determine the impact on registration fees and more information will be required to be able to determine that impact. It should be noted that savings through joint-working or merger may take some time to be realised and that there is also an opportunity cost to be factored into the balance.

7 Closing remarks

We are pleased that there is an opportunity for reform that places supporting professionalism so high in its ambitions. We have long stated that supporting professionalism is the most effective way that we can act to empower pharmacy professionals to provide safe and effective services and improve them. We remain committed to ensuring that the way in which we regulate pharmacy must improve the safe and effective care that people receive. We will continue to engage with people to ensure that regulation does this.

We have already made considerable progress since we were formed in 2010 to embody a regulatory approach that provides both assurance and drives improvement in the interests of patients. We have done much of that without the need for legislative reform. We will continue to act now, before any legislative reform comes so that our approach is more collaborative, more supportive of professionalism, informed further by data, well governed, efficient and effective so that we can continue to demonstrate to the public that the trust they have in pharmacy professionals and pharmacy is well placed.

8 Questions

Q1: Do you agree that the PSA should take on the role of advising the UK governments on which groups of healthcare professionals should be regulated?

It is for governments to determine which professions should be regulated and how they should be regulated. And we agree that the UK governments should seek advice on which groups of healthcare professionals should be regulated. In making decisions about which groups should be regulated, we believe there are some important tests that need to be met and the rationale for decisions should be clear and transparent. The tests are set out in para 4.2.

One of tests we outline is the need to be mindful of the perceived conflict of interest of the PSA, particularly given they are funded by the regulators (and therefore by those who are regulated) and also oversee voluntary accredited registers.

Q2: What are your views on the criteria suggested by the PSA to assess the appropriate level of regulatory oversight required of various professional groups?

Our experience in regulating pharmacy professionals and registered pharmacies means that we are able to see how some elements of the criteria, and the criteria as a whole, may not work in practice – given the way in which care and the context in which it is delivered continues to evolve. We are of the view that the criteria proposed for decision making require further thought and development in collaboration with others, for example patient and public representative organisations, professional leadership bodies and the regulated professionals themselves.

The proposed model for assessing whether professional groups should be regulated does not take account of the diversity of practice within and across professional groups in the evolving health and care system. Nor do the proposals take account of changes to the way in which professional groups may practise in the future. There is a risk that a professional group might be regulated because a small number perform a ‘high risk’ activity or are un-regulated because the majority perform a ‘low-risk’ activity. The amount of contact a professional has with patients and the public should not equate to a presumed ‘level of risk’. We have learnt from previous failures within the NHS that professionals who have relatively little contact with patients, but who have senior roles within hospitals and trusts can have a significant impact on the safe and effective care that people receive.

Within pharmacy practice, advancements in technology have meant that services are increasingly being provided at a distance, and with this come additional risks that need to be mitigated. Equally, the use of robotics within the dispensing service when properly applied can mitigate some of the risks around human error. These kinds of innovations demonstrate that a ‘risk’ profile does not remain static or

measurable at one particular point in time and underline further the need for any changes to the regulatory regime to be flexible in practice.

Q3: Do you agree that the current statutorily regulated professions should be subject to a reassessment to determine the most appropriate level of statutory oversight? Which groups should be reassessed as a priority? Why?

In making decisions about which groups should be regulated, we set out in para 4.2 some important tests that need to be met and the rationale for decisions should be clear and transparent. These included:

- For any decisions on de-regulation, consideration should be given not just to current roles but possible future roles to avoid short-sighted decisions.
- The impact of de-regulation on a professional group should be considered. The presence of a regulatory body may mean that other organisations, such as professional bodies, are not resourced to provide the services of a regulator. This may lead to negative unintended consequences for professional groups subject to de-regulation and the people to whom they provide services.

Decisions to de-regulate should be treated cautiously, and must involve collaboration with patients and the public, the professionals who are at risk of de-regulation and organisations that support those professionals.

Q4: What are your views on the use of prohibition orders as an alternative to statutory regulation for some groups of professionals?

When statutory regulation or accredited voluntary registers are not appropriate for groups, there would be advantages to the use of prohibition orders. We would support prohibition orders because it is right to consider not only traditionally defined professionals but also unregistered staff and their impact on the delivery care. We also believe it is a sound method to have a full range of options available when making decisions on how to protect the public.

We draw parallels here to our work on establishing disqualification procedures for pharmacy owners. We have not been able to use our disqualification powers in relation to registered pharmacies because the relevant legislation is very narrowly and prescriptively drafted. We have seen that this can undermine confidence, through misunderstanding of the powers we hold and the tests that must be applied. A pharmacy defence organisation has called for a review of our powers, and we believe a legitimate debate should be had.

If prohibition orders and negative registration were to be taken forward, further consideration will need to be given to ensuring that the legal framework is sufficiently flexible, and proportionate to be used

effectively to protect the public. In addition the practicalities of such a list, for example who administers the list and how decisions are made would need to be considered. Again, further collaboration with patients and the public and others will be necessary.

Q5: Do you agree that there should be fewer regulatory bodies?

Q6: What do you think would be the advantages and disadvantages of having fewer professional regulators?

It is a decision for the Governments on the future number and configuration of regulators. However we believe there are a number of tests that should be used to support any decision to make changes to the current system. Please see para 4.10 for further detail.

We also reject the notion of “a high street regulator”, which has sometimes been proposed as an option for merger, as it is not reflective of the many ways in which patients, the public and carers access healthcare services. If the definition of ‘high street healthcare’ means services available to the public in retail settings, that is in itself quite restrictive, and does not reflect ways in which access may occur. For example, within the context of pharmacy, services will be increasingly delivered online (both as clinical consultations and the dispensing of medicines), and delivered directly to a patient’s home, as well as a variety of other settings not on the high street , such as care homes.

We understand that one of the reasons for considering consolidation of regulators is the financial efficiencies of mergers. However we remain unconvinced about the evidence for this. We believe that many of the financial efficiencies could be gained through more effective collaboration and co-operation between regulators, using some of the examples set out in the consultation. And this can be done without the need for legislation.

Q7: Do you have views on how the regulators could be configured if they are reduced in number?

No. There are many ways in which the regulatory bodies could be configured. The focus of any reconfiguration should be whether a new configuration can evidence and demonstrate better outcomes for patients and the public than currently.

Q8: Do you agree that all regulatory bodies should be given a full range of powers for resolving fitness to practise cases?

Yes. We agree that all regulators should have the same tools at their disposal for managing and responding to concerns. Regulators should also be able to use other approaches for managing concerns as they consider appropriate for ensuring safe and effective care. For example, the regulators should be given the flexibility to develop alternative mechanisms for managing concerns that fall outside the current tools we use, whether that is mediation or something else. Otherwise there is a risk that we are

unable respond in a flexible manner as the types of concerns we receive change over time. A legal framework that provides us with the flexibility to design additional tools through rules and regulations would be welcome.

Fitness to practise currently can feel like an adversarial process, invariably causing anxiety and fear for those involved. Instead of focusing on the needs of patients, professionals are concerned about 'what the regulator will say or do'. Fitness to practise processes should be focused on the most serious types of concerns, and we believe that there should be further opportunity to look at the purpose of fitness to practise, not just the mechanisms for dealing with concerns. We can then use our other regulatory levers, such as revalidation, inspection and registration to support and promote professionalism with the aim of improving the quality and safety of the care that people receive.

Q9: What are your views on the role of mediation in the fitness to practise process?

We urge the UK governments to give regulators a legal framework that provides us with the flexibility to design additional tools through rules and regulations. Otherwise there is a risk that we are unable respond in a flexible manner as the types of concerns we receive change over time.

Q10: Do you agree that the PSA's standards should place less emphasis on the fitness to practise performance?

Yes. PSA standards should reflect the importance of all the regulators tools that contribute to safety and quality of care. While fitness to practise is an important part of the regulatory framework, it is of course not the only or most important of the regulators functions.

In addition, we would welcome additional oversight of our work to regulate registered pharmacies by the PSA.

Q11: Do you agree that the PSA should retain its powers to appeal regulators' fitness to practise decisions to the relevant court, where it is considered the original decision is not adequate to protect the public?

Yes, given our current statutory powers. However, if we were to be given a regulatory framework similar the GMC, with separation of investigation and adjudication and a right of appeal held by the GPhC, then this power may not be necessary.

Q12: Do you think the regulators have a role in supporting professionalism and if so how can regulators better support registrants to meet and retain professional standards?

Yes. We have long said that regulators have a role to play in supporting professionalism. We believe the professional knowledge, attitudes and behaviours of the people working in pharmacy offer the best

assurance to people using pharmacy services. Our most effective role is in helping to promote an environment in which professionalism can flourish.

Our standards for pharmacy professionals are outcome focused. They support and promote professionalism, making clear the expectations of patients and members of the public. The standards are not prescriptive but explain the attitudes and behaviours that pharmacy professionals must demonstrate. We have been aware that we must reflect what we say about our expectations of professionalism through all our work, for example when we manage concerns.

We have given examples of our work in this area in para 5.7.

Q13: Do you agree that the regulators should work more closely together? Why?

Q14: Do you think the areas suggested above are the right ones to encourage joint working? How would those contribute to improve patient protection? Are there any other areas where joint working would be beneficial?

We have responded to Q13 and 14 together. Working more closely together is undoubtedly a way in which the regulators can drive both greater efficiencies and effectiveness and has not required legislative change.

Healthcare professionals already work alongside one another and increasingly do so as health and social care become further integrated, for example through the work of the sustainability and transformation plans in England. Similarly, so too must the regulators, especially as distributed multi-disciplinary team working becomes more common and patients and the public will less easily recognise the boundaries between professions simply based on where people work and what people do. It is also notable that members of the public often will not recognise or indeed be interested in the differences between regulators. Many may see the role of professional and systems regulators as essentially being the same thing.

The purpose of regulators' collaboration needs to be clearly articulated so that it can be used as an appropriate test for evaluating efficiency and effectiveness. We believe the purpose of collaboration is to make the experience of engaging with regulatory bodies trusted, consistent, simple, and valued by members of the public, health professionals, their employers and any other party with a stake in regulation. Therefore, the focus on possible financial savings, which is likely to be a by-product with no guarantee that the benefit flows to patients, should not be a primary motivation or driver for that collaboration. Indeed it is at present unclear to us whether any projected savings would in fact materialise, or whether they would be significant enough to outweigh any disadvantages.

There are already many examples of effective co-operation between the health regulators but we agree and are keen to develop this further. We have, for example:

- Carried out joint inspections with other systems regulators, the Care Quality Commission and MHRA, when looking at services that cut across the GPhC and others; and
- Worked collaboratively with other professional regulators on areas such as conflicts of interest, the duty of candour and pandemic flu statements.

Mandating and requiring collaboration to be reported on through clear accountability processes could provide a useful opportunity for regulators to show how they are continuing to work together in the interests of patients and the public. Often the barrier to effective collaboration is felt to be moving decisions through differing governing structures, and the scheduling of such collaboration when each regulator works to a different timetable. Whilst one solution could be to look at new legislation that mandates such collaboration, or changes to the governance structures of the organisations we believe that there are other more efficient, less costly mechanisms that can be adopted much more rapidly. For example, through effective agreements on how certain types of joint-working are governed and led.

We strongly believe that the principle of joint working should not be limited to the professional regulators. The environments in which health professionals work are critical to delivering the context for professional, safe and effective care. If the environments are not supportive of the professionals who work in them, then the individuals in that place (both professionals and patients) suffer. As the regulator of both pharmacy professionals and registered pharmacies we believe the interplay between the regulation of people and places is fundamental to assuring and improving health and social care.

It is a decision for government on whether structural change is needed to foster more effective collaboration between regulators but we think the tests of any decision should be:

- That the views of the public and of the professions are taken into account.
- That the understanding of the context of health professionals' practice should not be lost in any future arrangements.
- That the outcomes achieved are enhanced trust, consistency, simplicity and value for the people who are regulated or rely upon regulation.

Q15: Do you agree that data sharing between healthcare regulators including systems regulators could help identify potential harm earlier?

The power of data to inform regulation is great, but it is also necessary to be realistic about what can be achieved. It is unlikely, based on the evidence that we have, that regulators will be able to use data in such a way to intervene before harm occurs in a particular instance. However, we can use our data, especially when shared, to support professionalism, empowering the people and places we regulate to

increasingly avoid the rare instances of harm and more widely improve the experience and outcomes of patients. There is also an opportunity for data driven regulation to provide us with a greater understanding of equality, diversity and inclusion issues and the effect of regulation on these.

We are committed to looking at how best we can share the data we hold and related insights across our functions, for example:

- Within fitness to practise, not only the learning from cases but also the information we hold about concerns that do not progress through the fitness to practise process;
- Through CPD returns and in the future revalidation; and
- Uniquely through our work in regulating registered pharmacies and inspection - information and data we hold about meeting our standards, and the publication of inspection reports.

Data sharing might also assist with targeting our resources more effectively. For example, we may be able to see patterns about certain geographies, programmes of professional education or types of service which suggest that we should scrutinise areas using our tools for assuring standards more frequently or more intensely. This is something we are currently exploring in our role as the regulator for registered pharmacies and as a result of the introduction of revalidation for pharmacy professionals.

Q16: Do you agree that the regulatory bodies should be given greater flexibility to set their own operating procedures?

Yes. Regulation is most effective at ensuring safe and effective care for people who use pharmacy services when it has a wide range of flexible regulatory tools that can be used to provide assurance and help to promote improvement, which reduces the risks of poor care in the future. This means we require a legal framework that provides us with the flexibility to regulate in a changing context, recognising the role of technology and innovation and the changing needs of a population that becomes ever more diverse and informed. This framework could be delivered through one or more section 60 Orders, and would not require a Bill. We also agree that flexibility must be balanced with clear arrangements for accountability. This would ensure there are checks and balances over our decisions and actions.

Q17: Do you agree that the regulatory bodies should be more accountable to the Scottish Parliament, the National Assembly for Wales and the Northern Irish Assembly, in addition to the UK Parliament?

Yes. Firstly we gladly offer consistent accountability to all legislatures on the breadth of our work. We welcome direct accountability to Parliament, the Scottish Parliament and the Welsh Assembly across the discharge of all of our functions to regulate pharmacists, pharmacy technicians and registered pharmacies.

Secondly we suggest that there may be different mechanisms for us to be held to account, perhaps some collectively with other regulators, which we would want to explore so that our work is more visible and can be tested consistently by governments, the public and the professions.

Finally, the culture of autonomy and accountability should run like a strong thread through the entire system. Health professionals and regulators should all have the flexibility to innovate, change and respond to the needs of the people, but do that within a clear framework of accountability. This culture is the one that will empower the whole system to adapt and improve safely, in the face of change.

Q18: Do you agree that the Councils of the regulatory bodies should be changed so that they comprise of both non-executive and executive members?

Our Council is constituted of seven pharmacy professionals and seven lay members, with a lay chair. The Council directs the strategy of the organisation and holds the executive to account for its performance. This method of governance has proved very effective because there is:

- Separation between the council and the executive providing clear lines of accountability. Without that separation it is much more difficult for the executive to be held to account for their actions.
- Balanced representation of the views of professionals and informed lay people.

Given the clear effectiveness of our current arrangements we will continue to value clear lines of accountability and a balance of professional and lay perspectives. The professional members are important and necessary members of the Council, who ensure that the context in which regulated professionals practice is understood, and whose presence on Council also enhances the confidence of the regulated professions in the deliberations and decisions made. It is for these reasons that a professional and lay Council is most valuable. When considering the number of Council members, it is important that the size is not so small that it precludes effective decision making and continues to ensure that the context of the regulated is considered. Decisions in the past have resulted in a reduction in the size of the Councils of regulatory bodies, and there is no doubt that this has improved governance overall; but the case for a further reduction is not made, in our view.

The breadth of the structure of our Council enables us to draw upon a wealth of experience of different models of governance, and we remain unconvinced of the potential benefits of a unitary board where the executive do not have any clear lines of accountability within the organisation. Such an arrangement compromises the accountability of the Chief Executive – who is then playing two roles of blurred identity, which have the potential to conflict.

Q19: Do you think that the views of employers should be better reflected on the councils of the regulatory bodies, and how might this be achieved?

We have explained why employers views should not be better formally represented in the membership of the councils of the regulatory bodies in para 6.19 and 6.20, but agree that it is essential that mechanisms exist to ensure that they are consulted on a regular basis, and that in particular cases of policy review, they play an active part in the formulation of new thinking.

Q20: Should each regulatory body be asked to set out proposals about how they will ensure they produce and sustain fit to practise and fit for purpose professionals?

All regulators should have a clearly stated strategy and model for the assurance they provide that the people and places they regulate are safe and effective. We have been developing our approach in this area and see the range of levers we have available to us as working collectively to provide that assurance. From initial education and training, registration and renewal of registration, revalidation for pharmacy professionals, quality assurance of registered pharmacies, and to investigating and acting upon concerns, the whole model drives assurance and improvement.

Q21: Should potential savings generated through the reforms be passed back as fee reductions, be invested upstream to support professionalism, or both? Are there other areas where potential savings should be reinvested?

It is not prudent to try to determine the answer to these questions absent the context in which any fee decision is made. Different circumstances will apply at different times; no Council could sensibly say in advance what the best approach would be. Certainly both these options may apply; as the question implies, there may be other demands on resource use which require particular investment decisions to be made. No advance formula can realistically help guide that.

Q22: How will the proposed changes affect the costs or benefits for your organisation or those you represent?

- an increase
- a decrease
- stay the same

Please explain your answer and provide an estimate of impact if possible.

The consultation does not set out a comprehensive model for the future of healthcare regulation. Therefore we are unable to answer this question.

Q23: How will the proposed changes contribute to improved public protection and patient safety (health benefits) and how could this be measured?

The consultation does not set out a comprehensive model for the future of healthcare regulation. Therefore we are unable to answer this question.

Q24: Do you think that any of the proposals would help achieve any of the following aims:

- Eliminating discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010 and Section 75(1) and (2) of the Northern Ireland Act 1998?
- Advancing equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it?
- Fostering good relations between persons who share a relevant protected characteristic and persons who do not share it?

If yes, could the proposals be changed so that they are more effective? If not, please explain what effect you think the proposals will have and whether you think the proposals should be changed so that they would help achieve those aims?

The consultation does not set out a comprehensive model for the future of healthcare regulation. Therefore we are unable to answer this question.

Meeting paper

Council meeting on Thursday, 08 February 2018

Public business

Engagement and communications report

Purpose

To keep the Council abreast of engagement and communications with stakeholders via a quarterly report.

Recommendations

The Council is asked to note this paper.

1. Introduction

- 1.1. This report outlines key communications and engagement activities since October 2017 and highlights upcoming events and activities.

2. Revalidation for pharmacy professionals

- 2.1 Following the December Council meeting, at which the Council approved the framework for revalidation and agreed the timetable for its implementation, we began the programme of communications for the implementation of revalidation.
- 2.2 We announced the Council's decision through a **press release**, which included quotes from the RPS and APTUK and resulted in media coverage across the pharmacy trade press. Our chair, chief executive and Head of Revalidation also took part in media interviews. We also informed all registrants of the development through an article in the December edition of Regulate and through our social media platforms.
- 2.3 We are now preparing for the next phase of communication with registrants, with the February edition of Regulate explaining how registrants can prepare for revalidation, and tailored communications going out via email from the end of February which will set out the timeline for each registrant.

- 2.4 Further supporting resources are being developed, and a letter will go out from early April reiterating what registrants are expected to do and when, and explaining how to log onto the portal where they can upload and submit records and renew their registration.

3. Department of Health consultation on reforming regulation

- 3.1. The Department of Health held its consultation on the reform of health professional regulation from 31 October 2017 to 23 January 2018.
- 3.2. At the time of launch, we **issued a statement** welcoming the consultation as an opportunity for positive reform. We also actively encouraged key audiences to participate in the consultation; including through an article in Regulate and an email to organisations we have worked with which represent patients and the public.
- 3.3. We issued a press release at the end of January to highlight key themes in our response to the consultation.

4. Focus groups on the publication of inspection reports

- 4.1. We organised three focus groups with members of the public so we could seek their views on the publication of inspection reports for pharmacies, and on the template for these reports. Three half-day focus groups were held in London, Cardiff and Glasgow between 27 November and 4 December 2017. Nigel Clarke and Jo Kember attended the focus group in Cardiff as observers.
- 4.2. Approximately 20 participants were recruited for each of the focus groups, through a market research agency and local organisations representing patients and the public.
- 4.3. In all three focus groups, there was a positive response overall to the draft reports, with most participants saying they found the reports clear and easy to read. There were also a number of suggestions for further improvement.
- 4.4. A report summarising the feedback from the focus groups has been drafted and the key findings will be shared with Council when it next considers publication of inspection reports.

5. BBC programme: *Boots: pharmacists under pressure?*

- 5.1. A BBC Inside Out investigation was broadcast on the BBC on 8 January in England, Wales and Northern Ireland, and on 10 January in Scotland. The programme focused on the concerns of a former Boots manager that staffing levels in Boots pharmacies were unsafe. The programme highlighted that the Boots manager had raised his concerns with us, and we had investigated his

concerns in detail, but concluded that there was not sufficient evidence to suggest a patient safety risk across the organisation.

- 5.2. We provided the programme with a statement from the chief executive and a significant amount of supporting information in relation to our investigation and our wider work, including our inspections of Boots pharmacies.
- 5.3. We also issued statements to the media both before and after the programme responding to the issues raised, which we also shared via social media. We are continuing to monitor and evaluate external reaction to the programme.

6. Dispensing Errors Order approved by Parliament

- 6.1. The Department of Health laid the Dispensing Errors (Registered Pharmacies) Order before Parliament on Tuesday 14 November. We issued a statement welcoming the laying of the order.
- 6.2. It was then debated in the House of Commons on 4 December and in the House of Lords on 6 December and was approved by both Houses. We contributed to a briefing prepared by the Department of Health for parliamentarians ahead of the debates.
- 6.3. In the December issue of Regulate, both Duncan's blog and the 'Focus on...' article highlighted the upcoming change in the legislation and encouraged everyone within pharmacy to consider what more can be done to report and learn from errors.

7. Ministerial reshuffle

- 7.1. The Prime Minister's recent reshuffle included the appointment of two new ministers of state for health and social care, and a new title for the Secretary of State and for the department. Rt Hon Jeremy Hunt MP now has an extended job title of 'Secretary of State for Health and Social Care' and the Department of Health has been renamed as the Department of Health and Social Care. This change indicates that full responsibility and leadership for social care will now sit with the Secretary of State, and emphasises the government's commitment to delivering greater integration of health and social care.
- 7.2. Philip Dunne MP, the former Minister of State for Health, has left the government. Philip Dunne MP had been responsible for health professional regulation, and was the minister overseeing the current consultation on the future of health professional regulation.

7.3. Caroline Dinenage, MP for Gosport, and Stephen Barclay, the MP for North-East Cambridgeshire, have both been appointed as new ministers of state for health and social care. We are now waiting for the Department of Health and Social Care to confirm the portfolios of the new ministers, and will then seek a meeting with the minister responsible for health professional regulation.

8. Recent events and meetings

8.1 Listed in Appendix 2 is a non-exhaustive selection of significant meetings held since October 2017.

8.2 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.

9. Upcoming events and activities

Please contact Laura Oakley, Stakeholder Engagement Manager, if you would like to attend any of these events:

Health Education England London and South East - Pre-reg Trainee Pharmacy Technician Education Leads meeting, 28/02/18 London
Os Ammar will be speaking on revalidation

Webinar on revalidation for commissioning teams, 05/03/18
Os Ammar and Keith Tapp will be participating in this webinar

National Institute of Health and Care Excellence meeting, 14/03/18 Manchester
Keith Tapp will present on revalidation

Robert Gordon University, 20/03/18
Lynsey Cleland will be speaking to 2nd year MPharm students about the GPhC

The GPhC will be participating in the following conferences in 2018:

Clinical Pharmacy Congress, 27/04/18-28/04/18 London

Association of Pharmacy Technicians UK (ATPUK) Annual Conference, 17/06/18-18/06/18
Glasgow

International Pharmaceutical Federation (FIP) conference (hosted by the RPS), 02/09/18-06/09/18 Glasgow

Pharmacy Show, 07/10/18-08/10/18 Birmingham

10. Consultations

10.1 Please see appendix 2 for the grid of active and new external consultations to which we have considered responding.

11. Equality and diversity implications

11.1 We continue to work to improve the accessibility and inclusiveness of our communications and our events. We ask participants in invites and pre-event communication to let us know about any requirements or support that they would need to ensure they can fully participate.

Recommendations

The Council is asked to note this paper.

Rachael Oliver, Head of Communications

General Pharmaceutical Council

rachael.oliver@pharmacyregulation.org

Tel 020 3713 7961

17 January 2018

Appendix 1

Events from 13 October 2017- 7 February 2018

Whittington Hospital visit, 16/10/17

Council members and staff visited Whittington Hospital to meet early years pharmacists and pre-registration trainees working in clinical and domiciliary settings

Defence Medical Services Pharmacy Conference, 26/10/17, 11:00-11:45 Lichfield, Staffordshire
Osama Ammar presented on key developments within pharmacy regulation

NHS Education for Scotland, 26/10/17

Inspector presentation to pre-registration trainees about the work of the GPhC

Annual Regulation Conference, 30/10/17 Edinburgh

Duncan Rudkin joined a panel to discuss responsive regulation and Osama Ammar presented on revalidation

Association of Independent Multiple Pharmacies member meeting, 31/10/17 Leicester

Osama Ammar lead a session about revalidation and other key developments in pharmacy regulation

Centre for Pharmacy Postgraduate Education National Multiples Meeting, 15/11/17 Coventry

Osama Ammar lead a discussion about revalidation

Association of Pharmacy Technicians UK North Merseyside Branch Meeting, 23/11/17 Liverpool

Osama Ammar presented on key updates in pharmacy regulation, including revalidation

Pharmacy Management National Forum, 10/11/17 London

Osama Ammar presented on 'Revalidation – what does the future hold?'

Centre for Pharmacy Postgraduate Education National Multiples meeting, 15/11/17 Coventry

Osama Ammar presented on revalidation and how the community pharmacy multiples can best support these changes

Buckinghamshire Local Pharmaceutical Committee, 15/11/17 Buckinghamshire

Inspector presentation on current work of the GPhC

University of East Anglia visit, 21/11/17 Norwich

Council members and staff visited UEA to meet with pharmacy school staff

University of Central Lancashire visit, 22/11/17 Preston

Council members and staff visit which included observation of Inter-Professional Education Chaos

day, tour of school, presentation about Comensus (patient involvement programme), discussions with students, staff and patients involved in the MPharm

Improving the impact of safety messaging in the healthcare sector: Shaping the future, 18/01/18
London

Martha Pawluczyk attended this conference aimed at developing solutions that make safety messaging as efficient and effective as possible to reduce the burden on healthcare staff and improve patient safety

APTUK leadership event, 20/01/18

Mark Voce presented an update on initial education and training standards for pharmacy technicians, and on revalidation

Camden and Islington Mental Health Trust, 25/01/18

Keith Tapp presented on revalidation

Islington Clinical Commissioning Group, 26/01/18

Os Ammar presented on revalidation

National Pharmacy Association webinar, 31/01/18

Os Ammar and Keith Tapp participated in this webinar on revalidation

Lo's Pharmacy Group Pharmacy Managers Meeting, 06/02/18

Helen Jackson presented on inspections and on revalidation

HEE Pre-registration Education Leads network event, 07/02/18

Damian Day presented on initial education and training for pharmacists, and on revalidation

Meetings

Listed below is a non-exhaustive selection of significant meetings since the last engagement and communications report to Council.

Initials are as follows: Nigel Clarke (NC), Duncan Rudkin (DR), Claire Bryce-Smith (CBS), Mark Voce (MV), Matthew Hayday (MH), Megan Forbes (MF), Lynsey Cleland (LC), Darren Hughes (DH)

Chair (Nigel Clarke):

- Visit to Whittington Hospital
- Rebalancing Programme Board Meeting (with MF)
- Association of Independent Multiple Pharmacies Annual Dinner
- Meeting with Chair, GPhC Appointments Committee
- Meeting with Chief Executive, Royal Pharmaceutical Society (with DR)
- Meeting with Chair, English Pharmacy Board, Director for England, Royal Pharmaceutical Society (with DR)
- Visit to Boots Dispensing Support Pharmacy, Preston
- Visit to University of Central Lancashire
- Human Health Antimicrobial Resistance Stakeholder Group Meeting
- Huxley Summit - The will of the people? Science and innovation in a post-truth world
- Kings Fund Annual Reception
- Meeting with Chief Pharmaceutical Officer Wales (with DH)
- Pharmacists Defence Association Reception - Patient Safety and Pharmacy (with DR)
- Meeting with Director of Professional Development, Chair, Faculty Board, Royal Pharmaceutical Society and Director, FIP Education Development, FIP Collaborating Centre (with DR)
- Meeting with Minister of State for Health and Chair, Professional Standards Authority
- Meeting with Chief Pharmaceutical Officer England
- Meeting with Baroness Meacher

Staff:

- Rebalancing Programme Board Meeting (MF with NC)
- CQC Online Provider Regulatory Forum (CBS)
- CQC National Cross Regulatory meeting (CBS)
- Meeting Minister for Welsh Language to discuss Welsh Language Standards (DH)
- Annual Regulation Conference (DR, LC, DH)

- Professional Standards Authority Report Launch - Untapped Resources: Accredited Registers in the Wider Workforce (DR)
- Meeting with Chief Executive, Company Chemists Association (DR)
- Meeting with Chief Executive, Royal Pharmaceutical Society (DR with NC)
- Professor Peter Noyce Memorial Lecture - Clinical pharmacy: past, present and future (DR)
- Meeting with Chair, English Pharmacy Board, Director for England, Royal Pharmaceutical Society (DR with NC)
- Meeting with the Welsh Language Commissioner (DH)
- PSA Seminar - Fitness to Practise Good Practice (CBS)
- RPS Wales Medicines Safety Conference (DH)
- Scottish Government conflicts of interest short term working group (LC)
- Meeting with CPhO Scotland (LC)
- Meeting with Chief Executive, Professional Standards Authority (DR)
- HEE Pharmacy Assurance Board (MV)
- Employer's Initiative on Domestic Abuse - END initiative Conference (CBS)
- Meeting with Dr Rik Greville, Director, ABPI Cymru (DH)
- Meeting with Healthcare Improvement Scotland (LC)
- Disclosure Scotland Stakeholder Advisory Board (LC)
- Meeting with Head of National Pharmacy Association Wales (DH)
- Meeting with Chief Executive, General Optical Council (DH)
- Welsh Pharmaceutical Committee - Ministerial Advisory Committee (DH)
- Pharmacists Defence Association Reception - Patient Safety and Pharmacy (DR with NC)
- Meeting with Russell Goodway and Mark Griffiths CEO and Chair of Community Pharmacy Wales (DH)
- Meeting with Director of Professional Development, Chair, Faculty Board, Royal Pharmaceutical Society and Director, FIP Education Development, FIP Collaborating Centre (DR with NC)
- Meeting with RPS Wales Director and Head of Policy (DH)
- CCA Professional Practice Group (CBS, MV)
- Meeting with Maree Todd MSP (LC)
- Chief Executives Legislation Group (DR)
- Health and Social Care Regulators Forum (DR)
- Meeting with Chief Pharmaceutical Officer England (DR)
- Meeting with Chief Executive, Health Education and Improvement Wales (DH)
- Meeting with Director of Defence Services, Pharmacists Defence Association (CBS, MH)
- Meeting with Chair and Director of Public Affairs, Pharmacists Defence Association (DR, CBS)
- Director of Resources Meeting (MF)
- Royal Pharmaceutical Society/UCL School of Pharmacy new year lecture - Reducing Health Inequalities (DR)
- Welsh Pharmacy Committee work planning workshop – Priorities for pharmacy (DH)

- All Wales Error Reporting Group (DH)
- Conference on priorities in primary care in Scotland (LC)
- Chief Executives Steering Group (DR)
- Avicenna Media Awards (MF)
- Cross Regulatory Research Group (CBS)
- Meeting with NHS Digital (CBS)

Active and new consultations

| Consultation title | Organisation | Brief description | Deadline | Consultation response status | Type of response | Lead | Reasons and further information | Link to consultation response |
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| GMC Telemedicine survey | International Association of Medical Regulatory Authorities | Europe Economics has been commissioned by the General Medical Council (GMC) to conduct a review of regulatory approaches to telemedicine, in order to contribute to the development of the GMC's policy in this area. | 20/09/2017 | Responded to | Online response form | LMC (Executive); SJ (Education and Standards) | The online survey has been responded to. | N/A |
| Consultation on a review of the Standards of Good Regulation | PSA | This consultation is asking for views on what the standards should cover and how they should be framed. The responses to this consultation will inform a second consultation on revised standards towards the end of the year. | 12/09/2017 | Responded to | Formal written response | LMC (Executive) | | https://www.pharmacyregulation.org/sites/default/files/document/gphc_consultation_response_standards_of_good_regulation.pdf |
| Services fit for the future | Welsh Government | The Welsh Government consulted on proposals to: - strengthen leadership in NHS organisations - introduce new duties of quality and openness - strengthen the voice of citizens in the way health and social care is planned and provided - design a clearer process for service change plans - improve the legal framework for the inspection and regulation of health services - establish a new independent body for | 29/09/2017 | Responded to | Formal written response | DH (Wales) | | https://www.pharmacyregulation.org/sites/default/files/document/response_to_welsh_white_paper_services_fit_for_the_future.pdf |

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| | | patient voice and regulation and inspection. | | | | | | |
| Security of Network and Information Systems | Department for Digital, Culture, Media & Sport | The actions proposed in this consultation are meant to help secure the UK's network and information systems, and everything that relies on that infrastructure. | 30/09/2017 | Responded to | Informal response (letter, email, other engagement) | OA (Education and Standards); CG (Governance) | | https://www.pharmacyregulation.org/sites/default/files/document/gphc_response_to_nis_consultation_-_29_september_2017.pdf |
| Consultation on the Authority's requirements for 2018/19 in respect of its regulatory oversight and standards functions | PSA | Consultation on the Authority's fee requirement for 2018/19. | 10/11/2017 | Responded to | Formal written response | LMC (Executive) | | https://www.pharmacyregulation.org/sites/default/files/document/gphc_response_to_psa_fees_consultation_2018-19_-_8_november_2017.pdf |
| Proposed options for changes to the Accredited Registers fee model | PSA | The PSA has launched a consultation into the options for financial self-sustainability of the Accredited Registers programme. They plan to become fully funded by income from registers by April 2021; the options within this consultation will allow this to happen. | 21/11/2017 | Responded to | Informal response (letter, email, other engagement) | LMC (Executive) | We limited our response to seeking confirmation from the PSA that these proposals would not have a direct | https://www.pharmacyregulation.org/sites/default/files/document/gphc_response_to_the_accredite |

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| | | | | | | | impact on our work and that the ongoing work on accredited registers will not be financed through the fees from the regulatory bodies. | d registers fees consultation - 23 october 2017.pdf |
| Proposed Draft Police Act 1997 and Protection of Vulnerable Groups (Scotland) Act 2007 Remedial Order 2018 | Scottish Government | The Scottish Government asked about proposed amendment to the Police Act 1997 and the Protection of Vulnerable Groups (Scotland) Act 2007. | 26/11/2017 | Responded to | Formal written response | LC (Scotland) | | https://www.pharmacyregulation.org/sites/default/files/document/gphc_response_to_draft_police_act_1997_and_protection_of_vulnerable_groups_scotland_act_2007_remedial_order_2018.pdf |
| Promoting professionalism, reforming regulation | Department of Health | This consultation seeks views on the reforms needed to help maximise public protection while supporting workforce development. The proposals aim to design a flexible model of professional regulation that secures public trust, fosters professionalism and improves clinical practice, while also being adaptable to future developments in healthcare. This consultation takes forward the Government's commitment to legislate to reform and rationalise the current system of regulation of healthcare professions. The responses to this consultation will allow the government to consider future options for the development of regulation | 23/01/2017 | Reviewed and being responded to | | OA, PW (Education and Standards) | | |

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| | | of healthcare professionals in the UK. | | | | | | |
| Facing the Facts, Shaping the Future: A draft health and care workforce strategy for England to 2027 | Health Education England | Health Education England has launched a consultation on their ten year plan to future proof the NHS and care workforce, which includes a section on pharmacy. Facing the Facts, Shaping the Future – a health and care workforce strategy for England to 2027 considers the outputs of major workforce plans for the priorities laid out in the Five Year Forward View – cancer, mental health, maternity, primary and community care and urgent and emergency care. There is a proposal for six overarching key principles that they believe should be adopted for all future workforce interventions. | 23/03/2018 | Reviewed and being responded to | | DD (Education and Standards) | | |
| Consultation on the statement on the role of the pharmacist | RPS | The RPS is consulting on a statement on the role of the pharmacist that was originally developed as a thought leadership paper by their Education Expert Advisory Group (which was composed of pharmacists from all sectors). With increasing health demands and expectations, describing how the pharmacist's unique role contributes to healthcare and society now and how it will develop and be applied further in the next five years is essential. The statement on the role of the pharmacist covers all sectors. It does not cover the scope of practice or other | 05/03/2018 | Being reviewed | | DD, MV, PW (Education and Standards) | | |

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| | | members of the pharmacy workforce. | | | | | |
| Brexit – medicines, medical devices and substances of human origin inquiry | Health Select Committee | The UK's withdrawal from the European Union (EU) and the European Atomic Energy Community (Euratom) means new regulatory arrangements must be put in place from 29 March 2019 to guarantee the safe and effective supply of medicines, medical devices, medical products and substances of human origin in the UK. Patients, the NHS and the UK's life science industry need certainty about what the UK's regulatory arrangements will be after Brexit and a smooth transition towards them. There are also major implications for the future of medical research and development. The Health Committee invites submissions on the options available to the UK Government, including the respective opportunities, risks and trade-offs involved. | 26/10/2017 | Reviewed but not responding | No response | MP (Education and Standards) | It is not appropriate for us to comment on the specific and technical aspects of the inquiry. However, we are interested in the consultation and will look out for further updates. |
| New proposal to expand the scope of performance assessments of providers regulated by the Care Quality Commission | Department of Health | This consultation is targeted at providers of health and social care services registered with CQC. It seeks their views as to whether it is appropriate for CQC to extend performance assessment and ratings to include independent community health services and independent doctors. | 06/11/2017 | Reviewed but not responding | No response | MV (Education and Standards) | The topic does not relate directly to our role or core functions as it is targeted at providers regulated by the CQC. However, we would be interested in the |

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| (September 2017) | | | | | | | outcome. | |
| UKPHR's Conditions of Registration 2018 | UK Public Health Register | UKPHR have begun a consultation to seek views on the introduction of Conditions of Registration 2018. | 14/12/2017 | Reviewed but not responding | No response | Policy & Standards team | The topic does not relate directly to our role or core functions and it is not appropriate for us to comment. | |
| The Regulation of Medical Associate Professions in the UK | Department of Health | <p>The Department of Health is seeking views on the following proposals:</p> <ul style="list-style-type: none"> - To introduce statutory regulation for Physician Associates - To seek further evidence on the most proportionate level of regulation for Physicians' Assistants (Anaesthesia) - To seek views on the position that statutory regulation of the Surgical Care Practitioner and Advanced Critical Care Practitioner roles is not proportionate, and whether alternative options for professional assurance should be considered. <p>The consultation also seeks initial views on prescribing responsibilities and on the most appropriate healthcare regulator should the four UK health departments decide to take forward statutory regulation for any or all of the 'Medical Associate Professions' roles.</p> | 22/12/2017 | Reviewed but not responding | No response | PW (Education and Standards) | The topic does not relate directly to our role or core functions. However, we will look out for any further updates which might be relevant to our work. | |

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| Regulation of nursing associates in England | Department of Health | The Department of Health is seeking views on amendments to the Nursing and Midwifery Order 2001, to regulate nursing associates in England. Amendments need to be made to the order to provide the NMC with the necessary legal powers to regulate the nursing associate profession. It is intended that aspects and regulatory functions of the legislation will apply to the nursing associate profession in the same way as for nurses and midwives. In amending the legislation, the regulatory framework for nursing associates will be similar to that of nurses and midwives, except where it is necessary to accommodate specific differences in the nursing associate profession. | 26/12/2017 | Reviewed but not responding | No response | PW (Education and Standards) | Similar to the above consultation, the topic does not relate directly to our role or core functions. However, we will be looking out for any updates which might be relevant to our work. | |
| Invitation to share your experience of a Professional Standards Authority's Accredited Register – Play Therapy UK (PTUK) | PSA | The Professional Standards Authority for Health and Social Care sets standards for organisations holding registers for health and social care occupations not regulated by law and accredits those that meet them. Play Therapy UK (PTUK) has submitted its intention to renew its accreditation, so the PSA is interested to hear stakeholders' experiences with them to confirm their ability to comply with PSA Standards. | 15/01/2018 | Reviewed but not responding | No response | LMC (Executive) | The topic of this consultation is outside of our scope as it relates to voluntary registers. | |
| Regulatory fees for 2018/19 – consultation | CQC | The CQC is seeking views on proposals to review the structure of their fees scheme to ensure that fees are charged and distributed proportionately within each sector. The proposals are based on what they have learnt and on changes to the health and care sectors and focus on these providers: - community social care - NHS GPs - urgent care | 18/01/2018 | Reviewed but not responding | No response | Policy & Standards team | It is not appropriate for us to comment on another statutory regulator's fees. | |

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| | | - NHS trusts | | | | | |
| Call for written views into the potential impact of Brexit on health | Scottish Parliament | <p>A Scottish Parliament Committee has issued a call for views on the potential impact leaving the European Union could have on health and social care in Scotland. The Health and Sport Committee would like to hear from people on the following questions:</p> <ul style="list-style-type: none"> • How could the potential risks of Brexit for health and social care in Scotland be minimised? • How could the potential benefits of Brexit for health and social care in Scotland be realised? • In what ways could future trade agreements impact on health and social care in Scotland? • What are your views on how common frameworks, to enable the functioning of the UK internal market in relation to health and social care in Scotland, should be agreed and governed? | 25/01/2018 | Reviewed but not responding | No response | LC (Scotland) | It is not appropriate for us to respond to the specific questions raised in this call for views. We believe that submitting a generic response may prompt further questions on matters which fall outside of our regulatory remit. In addition, discussions with Council on Brexit will not have taken place before submissions are required. |

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| Invitation to share your experience of a Professional Standards Authority Accredited Register - HGI | PSA | The Professional Standards Authority for Health and Social Care sets standards for organisations holding registers for health and social care occupations not regulated by law and accredits those that meet them. The Human Givens Institute (HGI) has submitted its intention to renew its accreditation, so the PSA is interested to hear stakeholders' experiences with them to confirm their ability to comply with PSA Standards. | 29/01/2018 | Reviewed but not responding | No response | LMC (Executive) | The topic of this consultation is outside our scope as it relates to voluntary registers. | |
| Raising concerns and making complaints about health, social care or education | NHS England | This survey is for children, young people and adults with a learning disability, autism or both, their families and paid carers. NHS England are carrying it out with the aim to add to what they have learned at events and meetings about people's experiences of raising concerns and making complaints. The feedback will help with a new project about raising concerns and making complaints called Ask Listen Do. | 31/01/2018 | Reviewed but not responding | No response | Policy & Standards team | This consultation is interesting to note but it is not appropriate for us to respond to. We will however identify any information that might be relevant to our work on raising concerns. | |
| Revised Freedom of Information Code of Practice | Cabinet Office | In response to the Independent Commission on Freedom of Information's report, the government agreed to update the Code of Practice issued under Section 45 of the Freedom of Information Act, to ensure the range of issues on which guidance can be offered to public authorities under the Code of Practice is sufficient and up to date. The government is now seeking views about this revised Code, particularly the areas highlighted in the consultation document. | 02/02/2018 | Reviewed but not responding | No response | CG (Governance) | We have considered the consultation and noted its proposals but we feel that it is not appropriate for us to submit a response. | |

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| Public consultation on fake news and online disinformation | European Commission | <p>The results of this public consultation will help assess the effectiveness of current actions by market players and other stakeholders, the need for scaling them up and introducing new actions to address different types of fake news.</p> <p>The consultation will collect information on:</p> <ul style="list-style-type: none"> - Definition of fake information and their spread online - Assessment of measures already taken by platforms, news media companies and civil society organisations to counter the spread of fake information online - Scope for future actions to strengthen quality information and prevent the spread of disinformation online. | 23/02/2018 | Reviewed but not responding | No response | RO (Communications) | <p>It is not appropriate for us to respond to this consultation but we shall be monitoring its outcome.</p> | |
| Conditions for which over the counter items should not routinely be prescribed in primary care: A consultation on guidance for CCGs | NHS England | <p>NHS England is launching a public consultation on reducing prescribing of over-the-counter medicines for 33 minor, short-term health concerns. The products have been chosen because they meet one of the following criteria:</p> <ul style="list-style-type: none"> - They treat a condition which is self-limiting and therefore does not require treatment; - They treat a condition which could be managed by self-care, i.e. a person suffering does not normally need to seek medical care; or - They have low clinical effectiveness but high cost to the NHS, e.g. vitamins/minerals and probiotics. <p>NHS England has partnered with NHS Clinical Commissioners to carry out the consultation after CCGs asked for a nationally co-ordinated approach to the development of commissioning guidance in this area to ensure consistency and address</p> | 14/03/2018 | Reviewed but not responding | No response | PW (Education and Standards) | <p>We would be interested in the outcome of this consultation, but it is not appropriate for us to comment on which items should or should not be prescribed.</p> | |

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| | | unwarranted variation. The intention is to produce a consistent, national framework for CCGs to use. Subject to the outcome of the consultation, the commissioning guidance will need to be taken into account by CCGs in adopting or amending their own local guidance to GPs in primary care. | | | | | |
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| Consultation response status | Type of response |
|---------------------------------|---|
| Being reviewed | Formal written response |
| Reviewed and being responded to | Online response form |
| Responded to | Informal response (letter, email, other engagement) |
| Reviewed but not responding | No response |

Meeting paper

Council on Thursday, 08 February 2018

Public business

Deputising arrangements for Chair of Council 2018/19

Purpose

To note the deputising arrangements for the Chair

Recommendations

The council is asked to note the arrangements for the deputy Chair.

1. Introduction

- 1.1. Council agreed in February 2010 to establish a rota of Council members to deputise for the Chair if required. It was agreed that a rota of volunteers, chosen at random, was more appropriate than a formal election process, given that the need for a deputy would arise only if the Chair was absent or unable to perform his duties. It would also avoid the impression that there was a “Deputy Chair” with a different role and status from other Council members.
- 1.2. It was also agreed that a rotation every six months, determined in advance, would allow arrangements to be made quickly, should the Chair be unexpectedly absent.

2. Deputising rota 2018/19

- 2.1. The deputising arrangements were used in 2017/18 at Council in September for the item on the Chair’s appointment for 2018.
- 2.2. Arun Midha chaired the discussion of this agenda item, which outlined the reappointment process for the Chair of Council in 2018. Nigel Clarke, the Chair, declared a conflict of interest and left the room.
- 2.3. The current rota expires at the end of March 2018. The new rota to cover the next twelve months is as follows (the rota to date is included for completeness):

| Name | Deputising starts | Deputising ends |
|------------------|-------------------|-----------------|
| Samantha Quaye | 01 Oct 2018 | 31 Mar 2019 |
| Joanne Kember | 01 Apr 2018 | 30 Sep 2018 |
| Mohammed Hussain | 01 Oct 2017 | 31 Mar 2018 |
| Arun Midha | 01 Apr 2017 | 30 Sep 2017 |
| Mary Elford | 01 Oct 2016 | 31 Mar 2017 |
| David Prince | 01 Apr 2016 | 30 Sep 2016 |
| Evelyn McPhail | 01 Oct 2015 | 31 Mar 2016 |
| Digby Emson | 01 Apr 2015 | 30 Sep 2015 |
| Berwyn Owen | 01 Oct 2014 | 31 Mar 2015 |
| Tina Funnell | 01 Apr 2014 | 30 Sep 2014 |
| Sarah Brown | 01 Oct 2013 | 31 Mar 2014 |
| Soraya Dhillon | 01 Apr 2013 | 30 Sep 2013 |
| Celia Davies | 01 Oct 2012 | 31 Mar 2013 |
| Gordon Dykes | 01 Apr 2012 | 30 Sep 2012 |
| Peter Wilson | 01 Oct 2011 | 31 Mar 2012 |
| Cathryn Brown | 01 Apr 2011 | 30 Sep 2011 |
| Liz Kay | 01 Oct 2010 | 31 Mar 2011 |
| Judy Worthington | 01 Apr 2010 | 30 Sep 2010 |

3. Equality and diversity implications

3.1. There are no specific equality and diversity implications.

4. Communications

4.1. Council members and staff should have a clear understanding of the arrangements for deputising for the Chair, if required.

5. Resource implications

- 5.1. These arrangements aim to provide cover for single events or short periods of time. Other arrangements would need to be put in place to cover any long term absence of the Chair.

6. Risk implications

- 6.1. If the Council does not have a process in place for the advance identification of a deputy, it runs the risk of having no leadership for a short period of time, should the position of Chair become vacant or the Chair be absent without warning for any reason.

7. Monitoring and review

- 7.1. The rota is considered annually.

Recommendations

Council is asked to note the deputising arrangements for the Chair.

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1 February 2018

Minutes of the **Audit and Risk Committee** meeting held on **Tuesday 23 January 2018** at 25 Canada Square, London at 11:00

TO BE CONFIRMED 22 MAY 2018

Minutes of the public session

Present

Digby Emson (Chair)
Helen Dearden
Mark Hammond
Jayne Salt

Apologies

Mohammed Hussain

In attendance

Duncan Rudkin (Chief Executive and Registrar)
Megan Forbes (Deputy Chief Executive and Director of Operations)
Claire Bryce-Smith (Director of Insight, Intelligence and Inspection)
Pascal Barras (Interim Head of Governance)
Ruth McGregor (Head of Finance and Procurement)
Bobbi Birk (Risk and Assurance Analyst)
Bill Mitchell (Moore Stephens)
Tim Redwood (Crowe Clark Whitehill)
Helen Dalrymple (Council Secretary)
David Hadjuk (Head of I.T.) – item 32
My Phan (Head of Data and Insight) – item 33

27. Attendance and introductory remarks

- 27.1. The Chair welcomed those present to the meeting. He offered congratulations on behalf of the Committee to Pascal Barras (PB), the new interim Head of Governance and thanked Matthew Hayday for all his work with the Committee. He also congratulated Bobbi Birk (BB) on her new role as Risk and Assurance Analyst. The Committee welcomed Tim Redwood (TR) who represented Crowe Clark Whitehill; this was their first meeting as external auditors of the GPhC.

28. Declarations of interest

- 28.1. Members were asked to declare any interests at the start of each item.

29. Minutes of the last meeting

- 29.1. **The minutes of the public session of the meeting held on the 25 October 2017 were agreed as a true record.**

30. Actions and matters arising

- 30.1. Duncan Rudkin (DR) informed the Committee that useful work was underway around the action referred to at minute 41.8. A 'never events' policy would be in place by April 2018 and this would be shared with the Committee.

ACTION: DR

- 30.2. All other actions were in hand or due to be covered at this meeting.

31. Internal audit performance report

- 31.1. PB presented **18.01.ARC.02** which provided a quarterly report on the progress of the internal audit plan and the follow up of recommendations.
- 31.2. The completion target had not been met due to some work being rescheduled to accommodate changes in the organisation's structure and to provide opportunity for those new in post to contribute. The timing of the audit of inspections had been moved. The first part was complete; the second part had been moved to accommodate changes in methodology.
- 31.3. The Committee sought assurance from the team and the internal auditors that the organisation had capacity for the work that was planned. Bill Mitchell (BM) confirmed that this was the case and that the scheduled audits were on track to complete as scheduled.

31.4. The Committee:

- i. **Noted Q3 2017/18 internal audit plan process; and**
- ii. **Noted the GPhC's performance in implementing agreed recommendations.**

32. Internal audit report: I.T. security

- 32.1. PB took members through **18.01.ARC.02**. David Hadjuk (DH) was in attendance for this item. Moving systems to the cloud marked a significant change in process. The auditors had been asked to challenge the design principles of the project.
- 32.2. The Committee asked for assurance around the security of data. DH explained that the data was protected by Microsoft and was also encrypted. There was a good relationship with the provider and automatic reporting with real time analytics highlighted any issues very early on.
- 32.3. The Committee discussed the problem of obtaining assurance on a specialist area which they had limited knowledge about. It was difficult to interrogate helpfully. The Committee agreed that they would like a proposal on ways that they could keep track of how actions suggested by the internal auditors on this report had been reviewed.

ACTION: PB

- 32.4. In terms of how the organisation compared with other healthcare regulators, BM described the GPhC as pioneering in that they were using a different model for their I.T. that was cloud based and 'off the shelf' and MF pointed to our approach being very similar to that taken by at least one other healthcare regulator.

33. Outstanding internal audit actions

- 33.1. Claire Bryce-Smith (CBS) gave a presentation to the committee that provided an update on the organisation's approach to work on data and insight and set out the way forward for dealing with the outstanding audit recommendations. CBS explained that it was necessary to develop a new strategic plan for GPhC's approach to Insight & Intelligence. The first diagnostic and scoping phase of work would last until June-July 2018 by which time we expect to have a new strategy approved by Council.
- 33.2. DR emphasised that when designing the scope of future audits the outstanding recommendations would be borne in mind to ensure that they had been fulfilled.
- 33.3. The Committee agreed with the approach that had been taken and felt that the process could now continue with a clean slate. They said that they wanted to remain sighted on any issues that came up. The Committee also noted that there are two check points recommended as part of the internal audit plan for next year.

- 33.4. BM assured members that this was sound from an internal audit point of view. In Q1 2018/19 work in this area would centre on ensuring that the intention described by the previous recommendations had been carried through. Strategy would now be at the forefront of the data and insight work and the auditors were content with this approach.
- 33.5. **The Committee approved the refresh of 'live' audit actions and their timescales.**

34. Internal audit plan 2018/19

- 34.1. PB took the Committee through **18.01.ARC.05**, the internal audit plan for the next year. The plan had been aligned with the strategic priorities of the organisation. The auditors had met with DR and Megan Forbes (MF) to obtain a high level view of audit activity. This had then gone to the senior leadership group (SLG) for their feedback.
- 34.2. A column on which strategic risk was addressed by the audit had been added. An exception had been found around Health and Safety and the discussion about compliance was ongoing.
- 34.3. BM told members that the auditors had aimed for a balance between delivery and systems in the plan. There were two key themes for this year; core processes such as registration and fitness to practise, and being able to provide assurance around cultural change and data & insight. While change was ultimately management's responsibility the auditor did have a role in providing assurance.
- 34.4. The Committee discussed how fitness to practise decision making was reviewed, and asked whether independent assurance was commissioned regularly. CBS confirmed that reviews of decision making had taken place, and this would be added to the assurance map that would come to the Committee in May.

ACTION: PB

- 34.5. Members agreed that they would not want to see any further delays next year; they looked forward to a review of I.T. security and felt that it may be a good idea for assurance work to be undertaken on the General Data Protection Regulation as it is due to come into force in May 2018.

ACTION: PB

- 34.6. **The Committee approved the internal audit plan for 2018/19**

35. External audit plan 2018/19

- 35.1. Tim Redwood (TR) presented **18.01.ARC.06**. The external audit plan for 2018/19 set out the scope of the audit and the approach that Crowe Clark Whitehill would take.

35.2. The Committee thanked TR for his comprehensive approach and looked forward to seeing him at their next meeting.

35.3. **The Committee noted the external audit plan 2018/19.**

36. Any other public business

36.1. The Chair thanked all concerned for their work and for providing assurance at the level that the Committee were looking for.

36.2. There being no further public business to discuss, the meeting closed at 12:25.

Date of the next meeting:

Tuesday 22 May 2018