

Council meeting

12 October 2017

14:00 to 15:30 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 September 2017</i>	Nigel Clarke
4. Actions and matters arising	Nigel Clarke
5. Analysis of the consultation on revalidation for pharmacy professionals <i>For noting</i>	17.10.C.01 Osama Ammar
6. Engagement with key stakeholders <i>For noting</i>	17.10.C.02 Rachael Oliver
7. Professional Standards Authority annual performance review <i>For noting</i>	17.10.C.03 Laura McClintock
8. General Data Protection Regulation (GDPR) <i>For noting</i>	17.10.C.04 Matthew Hayday
9. Change of external auditors <i>For approval</i>	17.10.C.05 Digby Emson
10. Any other public business	Nigel Clarke

Confidential business

11. Declarations of interest <i>Confidential items</i>	All
12. Minutes of last meeting <i>Confidential session on 07 September 2017</i>	Nigel Clarke
13. Confidential actions and matters arising	Nigel Clarke
14. Any other confidential business	Nigel Clarke

Date of next meeting

Thursday, 09 November 2017

Minutes of the **Council** meeting held on **Thursday, 7 September 2017** at 25
Canada Square, London at 14:00

CONFIRMED 12 OCTOBER 2017

Minutes of the public session

Present

Nigel Clarke (Chair)	Evelyn McPhail
Mary Elford	Arun Midha
Digby Emson	Berwyn Owen
Mark Hammond	David Prince
Mohammed Hussain	Samantha Quaye
Joanne Kember	Jayne Salt
Alan Kershaw	

Apologies

Elizabeth Mailey

In attendance

Duncan Rudkin (Chief Executive & Registrar)
Megan Forbes (Deputy Chief Executive and Director of Operations)
Claire Bryce-Smith (Director of Inspection and Fitness to Practise)
Francesca Okosi (Director of Organisational Development and Equality, Diversity and Inclusion)
Hugh Simpson (Director of Strategy)
Laura McClintock (Chief of Staff)
Matthew Hayday (Head of Governance)
Damian Day (Head of Education)
Dabrina Issakhany (Policy Manager – Education)
Terry Orford (Head of Customer Services)

Mark Voce (Head of Systems Regulation – Inspection)

Helen Dalrymple (Council Secretary)

34. Attendance and introductory remarks

- 34.1. The Chair welcomed all to the meeting. Apologies had been received from Elizabeth Mailey. The Chair sent her Council's best wishes for her recovery.

35. Declarations of interest

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

36. Minutes of the last meeting

- 36.1. **The minutes of the public session held on the 6 July 2017 were confirmed as a fair and accurate record.**

37. Actions and matters arising

- 37.1. Actions were all closed with the exception of minute ref. 31.6 which had been added to Council's forward agenda.

38. Standards for the initial education and training of pharmacy technicians.

- 38.1. Damian Day (DD) introduced **17.09.C.01** which presented to Council the final standards for the initial education and training of pharmacy technicians and proposed changes to the criteria for registration as a pharmacy technician.
- 38.2. DD explained that rather than providing guidance to run alongside these, an operational evidence framework had been devised which would be much more usable.
- 38.3. Implementation of the standards would be checked thorough accreditation. Course developers had been involved in drafting the standards.
- 38.4. DD highlighted that in iii. and iv. of the recommendations the frameworks that were referred to were one and the same. He also informed members that course developers had been involved in the drafting.
- 38.5. Dabrina Issakhany (DI) took members through the key changes that had been made to the standards since the last meeting.
- 38.6. 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. Mohammed Hussain, Berwyn Owen, Evelyn McPhail and Jo Kember declared an interest as registrant members.

- 38.7. Members were concerned about the timeframe for course development. They requested assurance that the new qualifications would be ready for September 2018 as per the proposed timeframe at the outset of the review of standards and this was confirmed.
- 38.8. Council asked for assurance that the GPhC would be able to pick up early any issues with providing support for those managing and delivering the course in understanding their role at 3.6 and the pre-registration trainee being supported as a learner in the workplace at 3.7 of the standards. DD explained that we may require this to be audited as part of the accreditation process.
- 38.9. Some members felt that standard 42 on drug interactions was too broad.
- 38.10. The term 'employer' should be used carefully as it could be interpreted as a corporation as well as a professional.
- 38.11. Members discussed how it would be possible to ensure that pre-registration trainee pharmacy technicians would always have the opportunity to work in multi-disciplinary environments. It could be difficult for some pharmacies to facilitate this.
- 38.12. Hugh Simpson (HS) responded that it was fundamental to pharmacy technicians' training that they be exposed to a range of experiences. DI explained that they envisaged a learning agreement between the learner and course provider that would ensure this. The evidence framework addressed this matter and explained that some exposure could be at a distance, conducted over the phone, for example.
- 38.13. Council asked that standard 7 be amended to be more specific so that the values and beliefs of the public were to be borne in mind.
- 38.14. Council agreed that minor amendments here and at section 7 of part two of the standards could be signed off as a Chair's action following the meeting.
- 38.15. Members discussed the implications of there being no minimum standards for qualification. DD assured Council that both pharmacists and pharmacy technicians pre-registration would be assessed and closely monitored in the quality assurance work stream with evidence based work.
- 38.16. HS told Council that registration criteria would be brought back to Council; these may include an indication of requirements for supervision and further information on required experience and competencies. The aim of the standards would be to enable flexibility and they would be evaluated to check this.
- 38.17. The evidence framework would be consulted upon and feedback requested from Council members. Council thanked the Education team for a very good piece of work.
- 38.18. **Subject to the agreed drafting changes Council:**
- i) agreed the new standards for the initial education and training of pharmacy technicians;**
 - ii) agreed to the proposed changes to the criteria for registration as a pharmacy technician;**

- iii) noted the approach to developing a supporting evidence framework
- iv) agreed to the production of a supplementary evidence framework to be approved by the Chief Executive and circulated to Council when complete and;
- v) noted the revised equality impact assessment and its implications for the GPhC's work

39. Registration Assessment

- 39.1. DD introduced **17.09.C.02** which updated Council on candidate performance in the June 2017 Registration Assessment. He said that he was speaking on behalf of the Chair of the Board of Assessors who would be attending the Council meeting in November to report on both the June and September sittings.
- 39.2. Digby Emson declared an interest in this item as a registrant and the chair of a training provider.
- 39.3. Members asked about the issue with Sikh candidates carrying the ceremonial kirpan to the registration assessment. DD acknowledged that this incident had highlighted a lack of legal knowledge used in the management of some assessment centre providers and said that this would need to improve.
- 39.4. Student feedback from the British Pharmaceutical Students' Association had highlighted the variability in provision for pre-registration students' preparation for the Assessment amongst training providers. DD explained that we currently advise students to approach the training providers as we do not manage the pre-registration process. The GPhC were, however, considering the feedback carefully and were meeting with national commissioning bodies to discuss further.
- 39.5. Council queried two of the tables. Table 5 indicated a lower pass rate for those aged 36 and over. Table 9 could be interpreted as indicating that graduates of some schools may be under performing. Members recognised that candidate performance in the assessment was affected by multiple factors; they agreed that the Council should be wary of drawing conclusions from one set of data and were assured that quality assurance processes were used to draw out any issues.
- 39.6. Table 7 showed first attempt pass rates by sector. Council asked whether there was concern about pre-registration students being signed off as ready for the exam, particularly in the community sector, when they were not. DD said that sign offs were under review by the GPhC and were under discussion with Health Education England (HEE). There was a high level of engagement with the HEE advisory board who were committed to driving up standards.
- 39.7. **Council noted:**
 - i. candidate performance data and the discussion of issues of potential wider relevance in this report; and
 - ii. the Board of Assessors' report to Council and the assurance it provides about the June 2017 sitting

40. Performance monitoring and annual plan progress report

- 40.1. DR presented **17.09.C.03**, which reported to Council on operational and financial performance and progress against the annual plan to the end of June 2017. This paper was working towards a new style of reporting and members were asked for their feedback on whether this was the information that they required.

Customer Services

- 40.2. Members registered their concern that performance figures were not improving. They recognised that the likelihood of this happening had been flagged up at a previous meeting by the Deputy Chief Executive. The contact centre was public facing and declining performance here could affect the organisation's reputation. It was noted that there was only one member of staff who had been in post for a year. In response Council questioned whether the recruitment process had been vigorous enough.
- 40.3. Terry Orford (TO) assured members that since June 2017 the team had stabilised and fewer complaints had been received. A root and branch review of the service model was being carried out. He acknowledged that it had been hard to get the right people for roles.
- 40.4. Megan Forbes (MF) explained that the majority of calls to the contact centre are about our processes; when these were improved it was anticipated that the volume of calls would go down and pressure on the contact centre staff would be reduced.

Fitness to Practise (FtP)

- 40.5. Council asked whether it would be possible to see a meta-trend of cases with more detailed analysis. Claire Bryce-Smith (CBS) told members that this would be included in a report to Council later this year.

ACTION: CBS

Inspection

- 40.6. Mark Voce (MV) drew members' attention to an error at table 3.4 where the information did not match the narrative below.
- 40.7. Council discussed whether de-motivation in the workforce may be picked up at inspection. MV explained that this would be picked up in conjunction with reading across the Standards more than had happened previously.
- 40.8. Members asked if they could be provided with data by different nations. MV agreed that this would be possible and CBS added that there was not much difference in the data sets.

- 40.9. **ACTION:** CBS

Human Resources

- 40.10. Council sought assurance on turnover. They discussed exit interview data and asked for an update on plans to reduce staff turnover and better understand absence data. Francesca Okosi (FO) agreed to provide this.
- 40.11. **ACTION:** FO

Management accounts

- 40.12. Members wanted to know whether next year's figures would be adjusted to take account of this year's current underspend. MF replied that there would be a discussion on financial strategy at the next meeting of the Efficiency and Effectiveness Assurance and Advisory Group (EEAAG). At the moment the organisation was fairly confident that it would come in on budget by the end of the year.

Annual plan progress report 2017/18

- 40.13. Members said that they found the report useful. There was some discussion on the development of the data and insight strategy. The scale of this work was wider than initially thought. Analytical capacity needed to be built up and this had practical implications for progress.
- 40.14. Council felt that the strategic aim of ensuring that the pharmacy team had the necessary knowledge, attitudes and behaviours could have more detail on how outcomes, and success, could be measured, identifying the benefits to cost and public safety in the revalidation project.
- 40.15. **Council noted and commented on:**
- i. **the performance information provided at appendix 1; and**
 - ii. **the report on progress against the annual plan at appendix 2 and 3.**

41. Chair appointment process

- 41.1. Chair Nigel Clarke left the room. Arun Midha chaired the discussion of this agenda item. DR presented **17.09.C.04**, which outlined the reappointment process for the Chair of Council in 2018.
- 41.2. Council asked that they be provided with a list of all members eligible to oversee the collection and assessment of evidence to support the reappointment and submit a recommendation to the Professional Standards Authority (PSA). These would be members who were already in their second term of office. Eligible members would then be able to submit expressions of interest to oversee the process. Once the expressions had been received, Arun Midha would confirm the two Council members who would take part.
- 41.3. **Council:**
- i. **agreed the process for the reappointment of the Chair of Council commencing in April 2018**
 - ii. **agreed that they would approve two Council members, from a list of those who met the eligibility requirements, to oversee the collation and assessment of evidence to support the reappointment process.**

42. Minutes of the Audit and Risk Committee meeting

- 42.1. The Chair returned to the meeting. Digby Emson, as Chair of the Audit and Risk Committee, took members through the minutes of the last meeting on 19 July 2017.

- 42.2. Members were advised that the process of selecting external auditors was complete and that they would soon be provided with a recommendation to appoint the successful candidate.
- 42.3. The main elements of the general data protection regulation (GDPR) presentation would be brought to Council this year.
- 42.4. **Council noted the minutes of the Audit and Risk Committee meeting.**

43. Any other public business

- 43.1. **There being no further public business to discuss, the meeting ended at 16:05**

Date of the next meeting:

Thursday 12 October 2017

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		Open	A plan with timescales is being developed for a qualitative analysis of FtP process.
7 Sep 2017	40.5	Performance monitoring and annual plan progress report: a meta-trend of FtP cases with more detailed analysis would be provided to Council later this year.	Claire Bryce-Smith	Dec 18	Open	A workshop on meta-analysis of data will be held later this year.
	40.8	Performance monitoring and annual plan progress report: It was agreed to provide inspections data by different nations.	Claire Bryce-Smith		Closed	This will feed into the development of the new style of performance monitoring report.
	40.10	Performance monitoring and annual plan progress report: It was agreed to provide an update on plans to reduce staff turnover and better understand absence data.	Francesca Okosi		Open	Francesca will give a verbal update on this at the October Council meeting.

Meeting paper

Council on Thursday, 12 October 2017

Public business

Analysis of the consultation on revalidation for pharmacy professionals

Purpose

To provide Council with an analysis of the recent consultation on the proposals for revalidation for pharmacy professionals (provided as an appendix to this paper).

Recommendations

Council is asked to:

- Note the analysis of the consultation on revalidation for pharmacy professionals (provided as an appendix to this paper);
- Discuss the key areas of stakeholder feedback; and
- Provide feedback on how to respond to the consultation analysis findings.

1. Background

- 1.1. It has become a widely accepted principle that health professionals need to keep up to date to deliver safe and effective care. Further, it is increasingly understood that to maintain public confidence, regulatory bodies working with health professionals must demonstrate that this happens.
- 1.2. A number of reports into high profile failures¹ in healthcare, predominantly although not exclusively involving medical practitioners, led to calls from governments, patient representative bodies and others for the health professional regulators to introduce reforms to provide assurance about their registrants.
- 1.3. In particular the Bristol Inquiry report made extensive recommendations about the need for all healthcare professionals to be subject to some form of regulatory scrutiny and revalidation. A UK white paper published by the Department of Health (England) with UK and cross party support, *Trust, Assurance and*

¹ www.bristol-inquiry.org.uk; www.shipman-inquiry.org.uk

*Safety - The regulation of healthcare professionals in the 21st century*² set out governments' expectations that all healthcare professional regulators would bring forward revalidation proposals in due course for their professions.

- 1.4. For some time the pharmacy professions have been required to undertake continuing professional development (CPD) and submit records to the GPhC (as well as the previous regulator the RPSGB). However, the Council made an early commitment to review the process by which the pharmacy professions provided assurance to the public, through the regulator, that individuals remained up to date in their knowledge and competence. This was in recognition that CPD alone was not consistent with the independent reports referenced above, or would meet the expectations of policy makers, governments or our oversight body the Professional Standards Authority.
- 1.5. Preliminary scoping work was carried out from 2011 to 2013 including a review of relevant research and reports before Council made a commitment at its meeting in November 2013 to develop a new framework for assuring the continuing fitness to practise of pharmacists and pharmacy technicians.
- 1.6. Council commissioned work from the executive of the GPhC to develop a new framework which would include three core elements, described at that time as “a peer review process”, “a review of continuing professional development (CPD)” and the use of “external performance indicators”.
- 1.7. Proposals were developed against a set of core principles set out below.
 - The primary role of continuing fitness to practise is to reaffirm that registrants continue to meet the core professional regulatory standards.
 - The framework will need to take account of the full range of roles and settings of pharmacy practice and as a result be based upon a common standard and flexible process and evidence requirements.
 - The framework will complement and where possible incorporate existing mechanisms provided by organisations within pharmacy that support continuing fitness to practise assurance.
 - Any framework would need to be appropriately tested, piloted and evaluated using robust evaluation criteria including impact assessment of intended and unintended consequences.
- 1.8. The work to research, test, pilot and evaluate proposals has been completed and the draft framework for revalidation for pharmacy professionals was subject to consultation from 24 April to 17 July 2017 (three months).
- 1.9. Appended to this paper is an analysis of the responses we received to the consultation and also a series of engagement events held during the consultation period. The paper provides a summary of the consultation, including what we consulted upon, how we conducted the consultation and engagement activities, who we heard from and what we heard. The consultation analysis report contains much more detail on each of the points raised in the summary below.

² <https://www.gov.uk/government/publications/trust-assurance-and-safety-the-regulation-of-health-professionals-in-the-21st-century>

2. Key themes from the responses to the consultation

General feedback on the proposals

- 2.1. The majority of respondents supported the overall proposals and comments were generally very positive. Respondents expressing positive comments were supportive of what they perceived to be enhancements in robustness, simplicity of the requirements for registrants, an improvement focus, moving away from a “tick box” approach, flexibility of the model, aligning with the standards for pharmacy professionals and personal scopes of practice. There was also support expressed for the inclusion of the peer discussion and the reflective account in the new model. The planned changes to the review and feedback processes were also thought to be more meaningful and engaging.
- 2.2. However, some concerns were expressed about the proposals and respondents raised a number of issues and queries about the new revalidation process. General opposition came from those who were happy with the current system and saw no need to change, and from those who questioned the requirement to record and submit any of their CPD referring to the additional burden that it generates. Some respondents were worried about how the changes would affect them, particularly those in non-patient facing roles, locums and older registrants.

Continuing professional development

- 2.3. Respondents generally expressed satisfaction with the proposals to revise the approach to CPD recording but requested clarity around the distinction between planned and unplanned learning entries.
- 2.4. **Recommended response:** We will enhance guidance materials to make the distinction between unplanned and planned learning clearer.

Peer discussion

- 2.5. Of the proposed changes, the introduction of the peer discussion generated the most feedback from both organisations and individuals with a large number of respondents having questions or concerns about the approach.
- 2.6. Although many respondents had positive comments related to peer discussion the following areas were raised for consideration:
 - 2.6.1. Choice and availability of a peer (particularly for pharmacy professionals who may be in more isolated roles).
 - 2.6.2. Further guidance on selecting an appropriate peer.
 - 2.6.3. Maintaining objectivity in the peer relationship and over time.
 - 2.6.4. Robustness of the proposed peer discussion as a mechanism for continuing assuring fitness to practise.

- 2.6.5. Quality and consistency of peers.
 - 2.6.6. Production of more guidance to support the discussions.
 - 2.6.7. Requiring a more structured and recorded conversation or possibly mandating 360 feedback models.
 - 2.6.8. The function of the peer discussion being misappropriated by some employers.
 - 2.6.9. The link between peer discussion and appraisal.
 - 2.6.10. That peer discussion would prevent pharmacy professionals undertaking their learning and development on their own which would have a resource implication.
 - 2.6.11. Confidentiality, conflicts of interest and data protection.
- 2.7. **Recommended response:** For the most part, these issues can be addressed through further guidance and information materials. We propose to produce this guidance as planned but also supplement it with communications and engagement with the most affected parties.
- 2.8. **Recommended response:** On the issues related to the format of the discussion and perception of rigour it is proposed that the form and structure of the peer discussion as consulted upon continues to be the one taken into implementation, but it is recognised that over time, as the sector adapts to the new requirements that Council may wish to enhance the model iteratively based on evidence collected through evaluation.
- 2.9. **Recommended response:** Working collaboratively with other pharmacy organisations so that they can support registrants to locate appropriate peers and engage with the process in the most meaningful way.

Reflective account

- 2.10. The reflective account appears to also have been welcomed by many respondents however the following matters were raised for consideration:
- 2.10.1. Registrants should be empowered to reflect on the standards they choose rather than the ones directed by us.
 - 2.10.2. More clarity was required over when registrants would know which of the standards were to be included in that year's reflective account.
 - 2.10.3. More guidance was requested on the form of a good or bad reflective account.
 - 2.10.4. Additional support may be needed for some registrants who are less familiar with reflective thinking.
 - 2.10.5. Reflection, being inherently subjective, may do little to support improvement.
- 2.11. **Recommended response:** For the most part, these issues can be addressed through further guidance and information materials. We propose to produce this guidance as planned but also supplement it with communications and engagement with the most affected parties.

Submission of records

- 2.12. Again, the majority of respondents appear to feel the change to annual submission of records is a positive one. However the following issues were raised for consideration:
- 2.12.1. Prevention of plagiarism and resubmission of old records each year.
 - 2.12.2. Life-long recording of learning and development given that records would only be maintained for 18 months.
 - 2.12.3. Requests for clarity over submission deadlines and also regular reminders.
 - 2.12.4. The need for a period of adaptation to the new requirements.
 - 2.12.5. That annual submission feels too onerous for some, particularly when compared to 3 or 5 year cycles in operation for other regulated professionals.
- 2.13. **Recommended response:** For the most part, these issues can be addressed through further guidance and information materials. We propose to produce this guidance as planned but also supplement it with communications and engagement with most affected parties.
- 2.14. **Recommended response:** We will work in collaboration with other pharmacy organisations, particularly those supporting life-long learning to promote opportunities to record learning in other places and also to simplify transfer of records to GPhC.
- 2.15. **Recommended response:** We are planning phased implementation over 2018-2020 to support registrants in their adaptation to the new requirements. We are also planning collaboration with other pharmacy organisations to support registrants to meet the new requirements.

Review of records

- 2.16. Many respondents agreed that the changes proposed improved the way in which records are reviewed and provides a more robust process. There was also support for the use of two reviewers in ensuring objectivity and increasing consistency in the review process. There were however a number of issues raised for consideration:
- 2.16.1. Concerns about the involvement of a lay reviewer and in some instances a pharmacy technician reviewer.
 - 2.16.2. Requests for clarity about the selection, skills and training for reviewers.
- 2.17. **Recommended response:** The involvement of lay people is a key improvement to include the views of members of the public in the review process. Additionally, allocation of the appropriate professional reviewer means a better understanding of the role of the professional whose records are under review. We will provide further clarity on the review process, selection, skills and training of reviewers in guidance and supporting information.

Feedback

- 2.18. There was considerable support for the introduction of tailored developmental feedback rather than the current percentage score. Issues for consideration raised in responses were:
- 2.18.1. Requests for more guidance and clarity over the timings and outcomes of feedback.
 - 2.18.2. Requests for clarity on the process for remediation and more information to be made available to support registrants in remediation.
- 2.19. **Recommended response:** Further guidance and supporting information will be produced on the feedback and remediation processes.

Resource implications and transitional arrangements

- 2.20. Mixed feedback was received on the resource implications of the new proposals. Many saw the proposals as a more streamlined process supported by technological improvements. The reduction in the number of CPD entries was seen as creating space for the introduction of the peer discussion and reflective account, meaning overall the new proposals would reduce the burden on pharmacy professionals. Similarly, the simplified process for recording would allow more time for registrants to focus on their work and their patients or service users.
- 2.21. However, these views were not shared by all and the following issues were raised for consideration:
- 2.21.1. There would be an additional time burden overall.
 - 2.21.2. Time would be required for adaptation to the new requirements.
 - 2.21.3. There were requests for protected learning time.
 - 2.21.4. The peer discussion was seen to have an impact on multiple pharmacy professionals and may have an impact on employers who would be required to consider back fill arrangements.
 - 2.21.5. There was concern that costs may increase at GPhC and there may be a resulting impact on the registration fee.
- 2.22. **Recommended response:** For the most part, these issues can be addressed through further guidance and information materials. We propose to produce this guidance as planned but also supplement it with communications and engagement with the most affected parties.
- 2.23. **Recommended response:** Evidence and modelling based on the test and pilot studies suggest that the time and cost implications of the new requirements are an improvement on the previous model of CPD. However, monitoring and evaluation of the proposals will be undertaken to ensure that, when scaled up to the whole register, there are no unintended time or cost implications.

3. Next steps

- 3.1. This paper presents the analysis of the responses to the consultation only. Following Council's deliberation over what we heard, it is intended that we will present the proposals (subject to any further work or amendments that Council may direct) at a later meeting for approval prior to implementation.

3.2. Following approval of the final version of the proposals, there will be a period of time allowed to make preparations both within GPhC and beyond. During this time we will produce further guidance and engage with the sector. We currently anticipate being able to launch the new recording tool and guidance in spring of 2018, allowing time for affected people and organisations to acquaint themselves with the new process and requirements prior to the first group of registrants who will be asked for submission of solely new format CPD for their renewal in autumn 2018. In autumn 2019 the first group of registrants will be asked to submit their full set of revalidation records alongside renewal of registration. By 2020, the revalidation framework will be fully introduced when the first reviews against the review criteria for all revalidation records will take place.

4. Equality and diversity implications

- 4.1. In all stages of our development work we have considered whether there are any significant equality implications, either positive or negative, for registrants or members of the public. Each phase of the three year development programme and some of the specific activities within the programme have warranted separate equality impact analysis reports, such as at the stage of consultation.
- 4.2. A full impact analysis has been prepared following the consultation on revalidation for pharmacy professionals which draws upon not only the information that was given to us through survey responses and engagement events, but also other information collected at earlier stages of the development programme. This report has been presented alongside the consultation analysis.

5. Communications

- 5.1. At this time, key stakeholders will have the analysis report shared with them (including the revalidation advisory group). The report will also be published online.
- 5.2. Communications planning is focused toward the activities that will follow any decision of Council rather than their consideration of the analysis report. Activities will be planned to ensure common and widespread understanding of the proposals and their impact on pharmacy professionals and the sector.

6. Resource implications

- 6.1. Resource implications are not directly imminent as a result of Council's consideration of the analysis report, however, there are some matters raised in the report which relate to resource implications for the sector, pharmacy professionals and the organisation upon which the Council may wish deliberate.
- 6.2. When the Council comes to deliberate on the final proposals for implementation there will be another opportunity to consider resource implications.

7. Risk implications

- 7.1. Risk management in relation to the formulation of the consultation analysis report has been applied through a robust methodology to ensure that the summary of the responses is accurate and does not mislead.
- 7.2. There are again, no imminent risks as a result of Council's discussion of the analysis report. However, the Council may want to consider if any risks have emerged from the issues raised by respondents and consider further mitigations to be put in place if required.

8. Monitoring and review

- 8.1. Depending on the Council's comments on the analysis report, it is intended that they will consider final proposals for approval at their meeting in December 2017.
- 8.2. If the Council decide to agree proposals at that time then a full programme of monitoring the early stages of implementation will be produced and the first steps will be taken to design a coherent strategy for ongoing and long term evaluation of the revalidation framework.

9. Recommendations

Council is asked to:

- Note the analysis of the consultation on revalidation for pharmacy professionals (provided as an appendix to this paper);
- Discuss the key areas of stakeholder feedback; and
- Provide feedback on how to respond to the consultation analysis findings.

Osama Ammar, Head of Revalidation

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2 October 2017

Analysis report on the consultation on revalidation for pharmacy professionals: what we did

1. Policy background

- 1.1. Between April and July 2017, we consulted on a proposed new framework for revalidation for pharmacy professionals, which is due for a phased implementation between 2018 and 2020. The new framework is intended to support pharmacists and pharmacy technicians in keeping their knowledge and skills up to date, while providing assurance to the public that they are doing so.
- 1.2. These proposals emerged from a three year development programme and a longer period of exploratory research into the methods we might use to provide further assurance that the trust in pharmacy professionals is well placed. We already had mechanisms, such as annual renewal and our current CPD scheme, to provide this assurance. However, it was clear that there were enhancements that we could make to our ways of working that would improve assurance and better reflect the changing expectations on regulators and pharmacy professionals from governments, members of the public, employers and the professions.
- 1.3. The proposals we consulted upon were rigorously tested over the course of the development programme through research, testing, piloting and evaluation. The consultation is one of the last steps to engage with people affected by the proposals to understand their impact prior to implementation.

2. Summary of our proposals

- 2.1. We proposed changing a number of things about how we work and what we ask pharmacy professionals to do in order to remain on our register and to provide further assurance that the trust in pharmacy professionals is well placed.
- 2.2. The changes we proposed were to:
 - reduce and simplify the recording requirements for CPD
 - introduce a peer discussion
 - introduce a reflective account
 - simplify the standards and guidance
 - ask for records to be submitted every year at the same time that pharmacy professionals make their declarations for renewal of registration
 - improve the review of submitted records and the feedback to registrants

- 2.3. As well as making the changes we consulted upon, we also highlighted changes to how we will work. These changes were intended to make the process of recording and submitting records to us easier and included:
- producing an integrated online recording tool so that pharmacy professionals can use one system to log into their account at GPhC to record entries and renew their registration
 - reducing the need for ‘dual recording’ by working with organisations who have their own learning and development portfolios – such as professional bodies, education and training providers and employers – so that records can be transferred easily into the GPhC online recording tool
 - introducing automated support for our registrants in the online recording tool so that simple errors in recording do not automatically lead to remedial action
 - introducing easier ways to report and provide evidence of circumstances that might prevent submission or complete submission of records at the time of renewal

3. About the consultation

1.1. Overview

- 1.1.1. The consultation was open for twelve weeks, beginning on 24 April and ending on 17 July 2017. To ensure we heard from as many individuals and organisations as possible:
- An online survey was available for individuals and organisations to complete during the consultation period. We also accepted postal and email responses.
 - We organised a series of stakeholder events aimed at pharmacy professionals, pharmacy service users, organisations and other interested parties.
 - We created a toolkit of materials for organisations to disseminate information about the consultation to their members, including a press release and a presentation.
 - We engaged with media outlets to encourage coverage.
- 1.1.2. For transparency, Appendix 1 provides a list of the organisations that have engaged in the consultation through the online survey, email responses and one-to-one meetings.

1.2. Online survey

- 1.2.1. The online survey asked questions about:
- the proposed framework for revalidation of pharmacy professionals
 - the impact of the changes on pharmacy professionals, employers and pharmacy services users.
- 1.2.2. We received **1,858** responses to the survey; the vast majority of these were collected via the online survey with the remaining responses received by post or email using the consultation document. Alongside these, we received a small number of responses from organisations writing more generally about their views.
- 1.2.3. Of those who submitted a written response, **1,785** were individuals and **80** were from organisations.

1.3. Stakeholder events

- 1.3.1. The questions in the online survey were also used as a structure for discussion in our stakeholder events, allowing us to capture people's views, and include them in our consultation analysis.
- We held four stakeholder events in London, Manchester, Cardiff and Edinburgh and spoke at 32 events and conferences across England, Wales and Scotland. These were attended by a mix of pharmacists, pharmacy technicians, people working in education and training, employers, pre-registration pharmacists, and representatives from professional bodies and trade bodies.
 - We organised four patient focus groups, held in London, Manchester, Cardiff and Edinburgh and held one-to-one meetings with three patient organisations who were unable to attend any of our other events.
 - We hosted an online webinar.
- 1.3.2. Around **2,450** individuals and representatives of organisations participated in these events.

1.4. Media coverage

- 1.4.1. The revalidation consultation was promoted through interviews, press releases and social media activity.

1.5. Advisory group

- 1.5.1. As well as formally consulting on the proposals, we have involved stakeholders throughout their development. This involvement took the form of an advisory group, chaired by Lord Kirkwood of Kirkhope and made up of representatives from the pharmacy sector and patients. The advisory group steered the work to research, test, pilot and evaluate the proposals. During the consultation period, advisory group members attended our stakeholder events and in many cases provided responses to the consultation as individuals or through their organisations.
- 1.5.2. For details of the members of the advisory group, please visit our website at <https://www.pharmacyregulation.org/advisory-group>

4. Our approach to analysis and reporting

4.1. Overview

- 4.1.1. Every response received during the consultation period including notes from stakeholder events has been considered in the development of our analysis. Our thematic approach allows us to represent fairly the wide range of views put forward, whether they have been presented by individuals or organisations, and whether we have received them in writing, or heard them in meetings or events.
- 4.1.2. An important part of this consultation was a self-selection survey. As with any consultation, we expect that individuals and groups who view themselves as being particularly affected by the proposals, or who have strong views on the subject matter, are more likely to have responded..
- 4.1.3. The consultation questions are provided in Appendix 2.

4.2. Quantitative analysis

- 4.2.1. The online survey contained a number of quantitative questions such as yes/no questions and rating scales. All responses have been collated and analysed including those submitted by email or post using the consultation document. Those responding by post or email more generally about their views are captured under the qualitative analysis only.
- 4.2.2. We are aware that organisational responses may represent a large number of individuals and so these have been reported separately in our quantitative analysis.
- 4.2.3. A small number (less than 30) of multiple responses were received from the same individuals. These were identified by matching on email address and name. In these cases, the individual respondent's most recent response was included in the analysis.
- 4.2.4. The tables contained within this analysis report present the number of respondents selecting different answers in response to questions in the online survey. The ordering of relevant questions in the survey has been followed in the analysis.
- 4.2.5. Skipped answers have not been included. Cells with no data are marked with a dash.

4.3. Qualitative analysis

- 4.3.1. This analysis report includes a qualitative analysis of all responses to the consultation, including online survey responses from individuals and organisations, email and postal responses and notes of stakeholder engagement events.
- 4.3.2. A coding framework was developed to identify different issues and topics in responses, to identify patterns as well as the prevalence of ideas, and to help structure our analysis. The framework was built bottom up through an iterative process of identifying what emerged from the data, rather than projecting a framework set prior to the analysis on the data.
- 4.3.3. The purpose of the analysis was to identify common themes amongst those involved in the consultation activities rather than to analyse the differences between specific groups or sub-groups of respondents.
- 4.3.4. The term 'respondents' used throughout the analysis refers to those who completed the consultation survey and those who attended our stakeholder events. It includes both individuals and organisations.

Analysis of consultation responses and engagement activities: what we heard

5. Views on the proposed revalidation process

The core questions in the consultation focused on respondents' views of the proposals. Responses were sought on questions relating to the steps in the process and the changes being made. These questions were open ended to enable us to capture detailed feedback and a wide range of views. This section provides an analysis of the themes that arose.

5.1. General feedback on the proposals

- 5.1.1. The consultation received a large number of responses which included diverse feedback on the new approach. There was consistency across the issues that emerged through the online survey and the stakeholder events and across the organisational and individual responses.
- 5.1.2. The majority of respondents supported the overall proposals and comments were generally very positive. The approach was seen to be more robust and structured and an improvement on the current system which was seen as a largely tick box exercise. Respondents referred to the new requirements as being more fit for purpose and providing more flexibility in how registrants complete their revalidation. There was broad support for the alignment with both the Standards for Pharmacy Professionals and each registrant's own scope of practice. Respondents agreed that the new requirements would ensure ongoing compliance with the Standards for Pharmacy professionals and would also provide assurance that registrants were keeping their skills and knowledge up to date. There was recognition that the addition of the peer discussion and the reflective account together with better review and feedback mechanisms would be beneficial for professional development.
- 5.1.3. There was agreement that the standards and guidance had been simplified and that the overall approach was clear and easy to understand for pharmacy professionals, employers and the public. The simplified and streamlined approach together with the emphasis on reflection was seen to be less prescriptive than the current requirements and therefore more meaningful and engaging for registrants.
- 5.1.4. However, there were some concerns about the proposals and respondents raised a number of issues and queries about the new revalidation process. General opposition came from those who were happy with the current system and saw no need to change, and from those who questioned the requirement to record and submit any of their CPD referring to the additional burden that it generates. Some respondents were worried about how the changes would affect them, particularly those in non-patient facing roles, locums and older registrants. The remaining concerns and queries were focussed on specific elements or steps in the process and are therefore explored in detail in the commentary below.

5.2. New CPD requirements

- 5.2.1. Both individuals and organisations were very positive about the proposals to reduce and simplify the recording of CPD. The reduction in the number of entries from nine per year to four per year was welcomed as fewer entries would mean quality rather than quantity and allow individuals more time to

reflect and learn from their CPD activities. There was agreement that the new requirements ensured a focus which was relevant to each individual's role as opposed to the current requirements which were described as a tick-box exercise that focused on process rather than value. Many respondents also commented on the importance of the reflective approach which has been emphasised in the new framework, especially in relation to the impact on patients and service users. It was understood that reflecting on practice in this way would help to secure benefits for those using pharmacy services.

- 5.2.2. There was some uncertainty around the introduction of 'unplanned' activities and the terms 'planned' and 'unplanned' entries. Some respondents wanted further clarification on the difference between these types of CPD. Similarly, some questioned the need to differentiate between the two as the requirements in relation to recording and reflecting were the same for both.

5.3. Peer discussion

- 5.3.1. Of the proposed changes, the introduction of the peer discussion generated the most feedback from both organisations and individuals with a large number of respondents having questions or concerns about the approach. For those supporting the peer discussion, it was seen to strengthen the current CPD process through the requirement to have input from another professional. This would enable pharmacy professionals to better share information, knowledge and different points of view. It was also seen to provide greater assurance to users of pharmacy services through the knowledge that someone else other than the registrant is involved in the process. Many highlighted the value of peer discussion as a learning and development activity that encourages reflection on one's own practice and helps to identify areas for development that may not be noticed independently. There was further support for peer discussion as it will help pharmacy professionals to improve standards within specialities through discussing with a peer who understands and shares their specialisms. A common theme was recognition that peer discussion will reduce the professional isolation experienced by some pharmacists and pharmacy technicians and will promote collaboration and inter-professional learning.
- 5.3.2. One of the most frequently raised issues regarding the introduction of a peer discussion related to the choice and availability of a peer. Respondents were concerned that some members of the profession may find it challenging to find an appropriate person with which to discuss their professional practice. This was cited as being of particular concern for more isolated workers such as those working in remote areas, owners of small community pharmacies and locums who will come into contact with an ever changing group of peers. For many there was unease and uncertainty about their ability to find an individual they could trust and with whom they could have an honest and open conversation. A large number of respondents also linked this to the issue of specialisms and the difficulty in finding a peer who had sufficient knowledge and experience of their specialist areas of practice. Concern was also raised by pharmacy professionals working in other sectors, those taking career breaks or unemployed registrants as availability of a peer would be particularly difficult.
- 5.3.3. Many respondents asked for further guidance on who would be considered an appropriate peer, whether this had to be a pharmacy professional or whether it could be another member of the healthcare team. There was call for more support from the GPhC in helping registrants to find a peer, especially those in more isolated roles. Some respondents were reassured by the different ways in which the peer discussion could be conducted, for example by Skype or by telephone and saw this as a mechanism for alleviating some of the obstacles to finding a peer. Several organisations saw the

potential for them to help pharmacists to identify a peer or to host opportunities for peer discussions at sector events and workshops.

- 5.3.4. An issue that was raised by a smaller number of respondents related to choice of reviewer and objectivity. The GPhC guidance recommends not using a peer who is a friend or family member. There were a number of calls from both organisations and individual respondents for this to be mandatory to ensure objectivity and remove any bias. Similarly some questioned the use of the same peer over a number of years as this could also decrease objectivity over time.
- 5.3.5. This links to a wider concern raised by many respondents over the robustness of the proposed peer discussion as a mechanism for assuring continuing fitness to practise. The main issue related to the fact that the content of the conversation is not submitted to the GPhC, and only confirmation that a discussion has taken place is required. Consequently there is no review or quality assurance of the peer discussion which led respondents to question its validity and purpose. Many felt that it could become a tick box exercise rather than a valuable discussion on professional practice. Some also questioned the rationale for allowing a spontaneous conversation to be permissible and were concerned that this would not be as robust or beneficial as a planned and structured discussion.
- 5.3.6. Respondents also expressed concern about the quality and consistency of the peers and suggested that training, guidance and support be made available. It was further suggested that there should be more stringent controls on who can act as a peer including mechanisms for ensuring they have appropriate knowledge and experience to fulfil the role. This would increase the quality, consistency and value of the peer discussion.
- 5.3.7. There were requests for more clarity on what a peer discussion should cover and how to carry it out. Examples of both a good and a bad discussion were asked for and some suggested the use of video clips to illustrate how a peer discussion should be conducted. There was a lack of clarity among respondents as to what was expected from the peer discussion and recognition that whilst it could be a very beneficial exercise, this was dependent on the quality of the discussion. Again, as the review process would not address the quality of the discussion, some concluded that the benefits could vary across the profession.
- 5.3.8. Suggestions on how to improve the peer discussion included the requirement for a thorough and accurate record of the conversation, the requirement for it to take place in a structured format with trained reviewers and the replacement of the peer discussion with a quality assured peer assessment or 360 degree appraisal system.
- 5.3.9. Another issue to emerge regarded the influence of employers over the peer discussion. There was concern that instead of creating a safe space in which professional practice can be discussed openly and honestly, employers may use the peer discussion for performance management purposes and even to admonish or discipline staff. It was suggested that this would impact on the ability of individuals to be honest and to discuss and learn from their mistakes. There was also concern that employers would dictate who the peer would be and the content of the discussions and could use it to achieve local objectives. It was emphasised that the discussion needs to be a supportive and professional conversation that focusses on learning and reflection. Mixed feedback was received regarding the links between peer discussion and workplace appraisals, with some respondents describing duplication and asking for alignment of the peer discussion with existing internal appraisal systems. Others felt strongly that the peer discussion should not be linked to appraisals, nor should it be carried out by a line

manager so as to maximise the opportunities for honest and meaningful reflection. It was suggested that guidance should highlight that a peer need not be from within the same organisation and that this should be actively encouraged.

- 5.3.10. A more general concern regarding the involvement of a peer was that registrants would no longer be able to complete all their CPD activities on their own and in their own time. Peer discussion was seen to move CPD activities into the work domain and many were concerned about the time available to complete the activities. Another resource implication was that it would involve the time of another individual and this could have a negative impact on both individuals and their employers.
- 5.3.11. Confidentiality, conflicts of interest and data protection were also themes that emerged in relation to the peer. Many registrants were concerned about their ability to discuss their work openly with a peer, due to patient confidentiality or non-disclosure agreements. There were also issues around how conflicts of interest would be addressed when selecting the peer. A small number were concerned about the GPhC storing personal contact details of their peer, how this would be stored securely and for how long. There were a few additional queries raised through the consultation regarding professional, personal and legal liability with respondents asking if the peer could be held liable should any problems arise with a registrant's performance.

5.4. Reflective account

- 5.4.1. Most respondents to the consultation welcomed the introduction of the reflective account and recognised the value of reflection in learning and development. It was seen as an improvement on the current system which does not encourage reflection and as a crucial element in improving outcomes for those using pharmacy services. There was support for the alignment of the reflective account with the standards for pharmacy professionals as a mechanism for increasing awareness and understanding of the standards and for alignment with individual practice. Organisations were particularly keen to see this upstream approach to regulation that encourages registrants to reacquaint themselves with the standards on a regular basis. Furthermore by focussing on the standards, it was generally agreed that the requirements for the reflective account were clear and relevant.
- 5.4.2. There were mixed views however regarding the choice of standard selected for reflection. Some respondents did not agree that the GPhC should be responsible for the choice of standard, instead arguing that pharmacy professionals should be empowered to select their own standard in order to ensure that it was closely aligned to their individual roles and responsibilities. There were also many requests for clarity on how and when registrants would be notified of the standard chosen for reflection each year. Similarly, more guidance was required on the GPhC's expectations of the reflective account such as the length, content and format. Many individuals requested examples of a 'good' and 'bad' account to be made available in order to help them submit compliant records.
- 5.4.3. There was concern that some registrants may struggle with reflection as they are not used to this approach to their work, with older registrants and pharmacy technicians the most frequently cited groups in this regard. Additional support was requested for these groups, or for any individuals unused to reflection.
- 5.4.4. A small number of registrants were against the introduction of reflection arguing that reflective accounts are inherently subjective and questioning their value in improving practice.

5.5. Submission of records to the GPhC

- 5.5.1. The vast majority of respondents supported the move to annual submission of records instead of the previous requirement for records to be called on a 5-yearly basis. There was general opinion that whilst registrants are carrying out CPD regularly throughout their careers, the current system encourages recording and reflection on activities only when records are called. Smaller, annual submissions would avoid backlogs and would be more practical for managing workloads. This would also help to embed CPD and reflection in day-to-day practice and would ensure records are completed in a timely manner. Furthermore, many agreed that regular recording would ensure that proof of competency is current and up-to-date. Overall the new approach was seen to reduce and simplify the recording of CPD activities with much support for the reduction in dual recording through integration with other tools from professional bodies, education and training providers and employers. The move to a central depository for recording and storing CPD activities and for registration and renewal was welcomed by many.
- 5.5.2. Whilst many agreed that the new platform for recording CPD would be easier and more streamlined than the current system, there were some concerns raised through the consultation. Some respondents were concerned about the issue of detecting plagiarism and requested for there to be inbuilt anti-plagiarism software. Linked to this, there were questions on how to prevent the resubmission of old records as the new system will only store records for 18 months. A number of respondents were concerned at the loss of a permanent recording place for all CPD activities and the impact this would have on their ability to collate and retrieve existing records for other purposes. It was suggested that records should be stored for longer than 18 months, be easily retrievable, and that there should be the ability to store all CPD activities and not just those that are selected for submission to the GPhC. More general concerns regarding storage of data included questions on how data would be stored, for how long and the implications in terms of confidentiality and data protection.
- 5.5.3. Respondents stressed that the new recording system must be user-friendly and easily accessible from all devices and it was suggested that the GPhC could develop an App to improve accessibility. Queries were raised about which tools would be integrated to reduce dual recording and for more guidance on how such tools could be adapted. There were also a number of requests for the recording platform to be integrated with the RPS Faculty portfolio and it was suggested that further engagement with professional bodies and employers would eliminate more duplication of entries.
- 5.5.4. Many respondents expressed confusion about the process of submission at the time of renewal and how this would work in practice with the main concern being at what point in the renewal process the records would need to be submitted. Respondents commented that submission of all records at the same time as renewal could become burdensome and many were unaware that recording could take place throughout the year. Further guidance on the timelines for submission was requested. There were also requests for regular reminders when submission is due and for a sufficiently flexible timeframe for submission so as not to impact on workload. Similarly, respondents were concerned about the initial time it would take to get used to the new system and agreed that support during the transition phase was essential.
- 5.5.5. A small number of respondents disagreed with the move to annual submission, citing this as being too onerous and out of line with other healthcare professionals who undergo revalidation on 3-yearly or 5-yearly cycles.

5.6. Reviewing records

- 5.6.1. Many respondents agreed that the changes proposed improved the way in which records are reviewed and provide a more robust process. The current review of records was mostly seen as a tick box exercise that ensured registrants had followed the process for submitting CPD rather than providing a qualitative review of the activities carried out. The move towards more detailed scrutiny of records was therefore welcomed and seen as introducing quality assurance and rigour to the process. There was also support for the use of two reviewers in ensuring objectivity and increasing consistency in the review process.
- 5.6.2. There were mixed views about the inclusion of the lay reviewer. Many saw this as bringing a balanced approach between the views of the profession and the views of patients and the public. For those in agreement there was strong support for the lay reviewer in representing the needs of patients and for ensuring the needs of service users are central to the process. This was seen as providing broader assurance than the professional view alone would bring. Those who objected questioned the ability of the lay reviewer to understand and comment on the professional practice of registrants, particularly the more technical and complex elements. Professional expertise was seen as essential to making reasoned judgements and for providing meaningful feedback on the content, accuracy and relevance of activities and the involvement of the lay reviewer was therefore viewed as tokenistic.
- 5.6.3. There was more general feedback about the selection of reviewers and how to ensure that they had sufficient expertise to review records, particularly for those individuals in specialist areas and senior positions. A small number of respondents argued that only pharmacists should be used as reviewers. Many respondents stressed the importance of having sufficient breadth of experience within the pool of reviewers and for training of reviewers to be robust in order to ensure a consistent approach. This was seen as especially important for lay reviewers and there were calls for the selection criteria and recruitments process to be made explicit and for the role and responsibilities of both reviewers to be more transparent. Issues of confidentiality and conflicts of interest must also be addressed in the recruitment and selection of reviewers.
- 5.6.4. Although it was not subject to consultation at this time because of a previous consultation held in 2016, many individuals welcomed the targeted and random review of records as an improvement on the previous method of calling every registrant's records on a 5-yearly basis. Those supporting the change were satisfied that this provided sufficient assurance. However, the new sampling approach was also met with some opposition and uncertainty. The 2.5% sampling approach was viewed by some as too low as it could result in some registrants not having their records called for up to 40 years. There were suggestions to increase the sample size to address this. Other respondents requested guidance on how risk would be assessed and targeted and for clarity on how the random sampling would work. A small number suggested there should be more assessment of risk when calling records and low risk registrants should be exempt from review.

5.7. Feedback to registrants

- 5.7.1. There was considerable support for the introduction of tailored developmental feedback rather than the current percentage score. It was generally acknowledged that the proposals will produce better quality feedback that will be more meaningful and constructive for registrants and will aid them in their professional development and day-to-day practice. It was further agreed that the introduction of generalised feedback for those registrants not called for review was a positive step towards raising

standards across the profession. However, there was recognition that this would not be as beneficial as personalised feedback and some registrants expressed the desire to be included in the sample for review.

- 5.7.2. It was noted that the value of the feedback lies in both its quality and timeliness with the need for sufficient detail to have an impact on learning and development. Some asked for more guidance on the format the feedback will take before they were able to assess its usefulness and others asked for clear timelines for the review and feedback process. There was also confusion for some respondents about the feedback they will receive if not called for review and greater clarity was requested.
- 5.7.3. There were a number of comments around the process for remediation which highlighted a lack of clarity on what this entailed and how it would be communicated to registrants. Respondents requested guidance on what happens if unsatisfactory practice is identified. A small number of organisations described the need to work in partnership with employers to ensure that registrants are supported to address any deficiencies and it was suggested that signposting to support networks should also be provided.

5.8. Resource implications

- 5.8.1. Mixed feedback was received on the resource implications of the new proposals. Many saw the proposals as a more streamlined process supported by technological improvements. The reduction in the number of CPD entries was seen as creating space for the introduction of the peer discussion and reflective account, meaning overall the new proposals would reduce the burden on pharmacy professionals. Similarly, the simplified process for recording would allow more time for registrants to focus on their work and their patients or service users.
- 5.8.2. However, this view was not shared by all and there was concern that the new requirements would take longer to complete and would therefore create an additional burden on already busy professionals. Many respondents commented on the additional time that would be required to complete all three elements of revalidation and to record and submit on an annual basis. It was unclear to some respondents how the reduction in dual recording would reduce the bureaucratic burden as records must still be transferred from one system to another. There was also concern about the time required to adopt and adapt to the new system.
- 5.8.3. Pharmacy professionals described having to complete the current CPD requirements in their own time due to work pressures and in some cases due to a lack of support from their employers. Many respondents therefore highlighted the need for protected time at work to enable them to carry out the activities and to record and submit their records. There were several requests for protected time to be made a mandatory requirement for employers.
- 5.8.4. There was particular concern about the introduction of the peer discussion as this will need to be completed during work time and will also involve the time of another individual thus adding to the workload and pressures of two people. There were also questions around the cost implications for employers and pharmacy owners as the additional work may require extra staff to provide cover or backfill.
- 5.8.5. Respondents highlighted the resource implications for the GPhC such as the increased cost of having two reviewers and questioned whether this would result in an increase in their registration fees. There was also concern about whether there were sufficient resources in place to deal with busy periods such

as December when large numbers of registrants are due for renewal. Overall, there was general assurance that the proposals had been costed effectively and would result in savings for the GPhC due to the sampling approach.

5.9. Transition

- 5.9.1. Many comments were received regarding the transition process for introducing the new revalidation requirements. There was a lot of support for the phased approach which would allow registrants time to adapt and gain familiarity with the new system. There was agreement that the proposed timescales were sufficient to enable a smooth transition and for support mechanisms to be put in place. However, many respondents did express concern about the difficulties of adopting the new system and the possible time implications involved as they adapted to the new requirements. There were many queries about when the changes would happen and further clarity on timescales and the transition process was requested. A particular concern was what would happen to old records and whether a combination of old and new records would be eligible for submission during the first year. Specific comments were made around how the changes will be communicated and emphasis on the need for clear communication and promotion to all pharmacy professionals.
- 5.9.2. Linked to the feedback around the transitional arrangements were requests for general guidance and support. A number of requests were made for training and support to be available in addition to guidance for those who may struggle with meeting the new requirements or may need support in the transition phase. Workshops and briefing sessions were given as examples of how the GPhC could support registrants.

6. Providing assurance

6.1. Assurance of fitness to practise

- 6.1.1. Respondents were asked if they thought the changes will help to support registrants in their practice and provide assurance that pharmacy professionals remain fit to practise.

	Individuals	%	Organisations	%
Yes	1224	70%	60	86%
No	535	30%	10	14%
Total responses	1759		70	

- 6.1.2. Overall, a large majority of both individuals (70%) and organisations (86%) agreed that the changes will help to support registrants in their practice and provide assurance that pharmacy professionals remain fit to practise. One of the main reasons given for this was that the new approach was more robust than the current requirements due to introduction of the peer discussion and reflective account. Respondents agreed that the use of a variety of mechanisms created a broader range of assurances of pharmacy professionals' fitness to practise. Furthermore, the move to annual submission was seen to provide greater assurance that knowledge and skills are updated on a regular basis and not every five years when called for review. Similarly, having a mechanism whereby all pharmacy professionals, and not just those being called for review, must submit their records gives greater assurance across the profession as a whole. The emphasis on reflective practice and the links to the standards for pharmacy

professionals were seen as a more valuable and meaningful approach to CPD than the current process-driven requirement and thus would support and enhance practice.

- 6.1.3. For the smaller number of respondents who disagreed with the question above, a variety of issues were raised including the robustness of the process. The requirements rely on self-declaration and some respondents questioned whether registrants would be able to fabricate or exaggerate their activities. These respondents called for greater external scrutiny of the evidence in order to increase the assurances it provides. There was particular concern about the robustness of the peer discussion due to the general lack of quality assurance regarding the content and quality of the discussions and the choice of peer. There were also comments that the introduction of the lay reviewer would reduce the robustness of the review process due to their lack of technical expertise and that this could also affect the quality of feedback in supporting registrants in their practice.
- 6.1.4. Another concern for respondents was the issue of detecting impaired practice particularly at the early stages. Respondents referred to the ability of registrants to complete poor quality records, to pass the automated submission tests and then not get their records called for review for many years as contributing to this lack of rigour in detecting poor practice. Others referred to fitness to practise as a much broader issue that goes beyond completion of CPD records.
- 6.1.5. This linked to a wider theme concerning the purpose of the revalidation process. There were mixed views on the level of assurance the process should provide. Some viewed the activities as a mechanism for developing, reflecting on and improving their practice. Others saw it as a means of assessing the competency of pharmacy professionals much in the same way that doctors are required to go through a formal revalidation process. Several organisations questioned the use of the term 'revalidation' on the basis that they perceived this as implying formal appraisal by a senior professional. As a result the term suggests greater assurance than the process offers. This was echoed in the individual responses where the level of assurance was questioned due to the lack of formal assessment of skills and knowledge. Several organisations saw the proposals as a step towards a full revalidation process, whereas other respondents requested clearer communication on the specific meaning, nature and assurance the scheme is intended to offer.
- 6.1.6. Respondents also referred to the development and pilot phase as increasing their confidence that the proposals would meet their aims of supporting registrants and assuring they are fit to practise. However, others felt there was insufficient evidence that the proposals offered greater assurance than the current system both in terms of patient safety and support for pharmacy professionals
- 6.1.7. Some respondents commented that the proposals were still too focussed on process rather than improving practice and patient outcomes. There were suggestions of how the process could be better utilised for improving practice such as providing evidence that each of the standards for pharmacy professionals has been met. Another suggestion was to incorporate feedback on performance from other members of the multi-disciplinary team and from patients and service users.
- 6.1.8. A theme to emerge in relation to proving assurance was the flexibility of the proposals and their applicability to all registrants. There was concern regarding the 'one size fits all' approach with some respondents commenting that the proposals were not appropriate for those in more senior roles, such as superintendents and chief pharmacists suggesting a different revalidation framework is used to assess and assure their suitability for their positions of responsibility. Similarly, for those in non-patient facing roles, there was considerable feedback that the framework was not appropriate due to its

emphasis on the impact on patients. A small number of respondents suggested that the proposals were less appropriate for pharmacy technicians due to their different roles within the healthcare team. It was also commented that the framework must be sufficiently flexible to adapt to the emerging roles in pharmacy particularly those in advanced practice.

- 6.1.9. A final theme under assurance of fitness to practise was the issue of risk. There was concern that the random sampling process does not address risk and so may result in impaired performance going unnoticed for many years. There was also concern that the framework as a whole does not have mechanisms for identifying and responding to high risk areas or the emergence of new risks. Whilst many respondents agreed that registrants need to be responsible for their own learning and development, there were also calls for this to be balanced with a focus on areas identified as high risk.

6.2. Assurance to users of pharmacy services

- 6.2.1. Respondents were asked if they thought the revalidation framework overall will achieve its aim of providing further assurance to users of pharmacy services.

	Individuals	%	Organisations	%
Yes	1090	62%	54	79%
No	670	38%	14	21%
Total	1760		68	

- 6.2.2. 62% of individuals and 79% of organisations agreed that the revalidation framework will achieve this aim. These figures illustrate support from a majority of individuals and organisations, but also demonstrate that there was more uncertainty regarding the ability of the framework to provide assurance to pharmacy service users as compared with general assurance around fitness to practise (see 6.1 above). Many of the same issues identified in 6.1 were mentioned in relation to assuring service users but there were a number of additional issues specifically relating to patients and service users.
- 6.2.3. For those agreeing that the framework provides further assurance, there was support for the introduction of the peer discussion as this would strengthen the public's confidence through the knowledge that another professional has been involved in reviewing a registrant's practice. There was also recognition that the involvement of service users both in the development of the proposed framework and in the ongoing review of records would increase levels of assurance through ensuring that the needs and views of service users are represented. The framework was seen to enhance trust between pharmacy professionals and service users although there were also comments that public trust in pharmacy was already high and therefore further assurance was unnecessary.
- 6.2.4. For those who did not agree, many comments particularly from individuals related to perception of the public's awareness both of the profession as a whole and of the role of revalidation. Respondents proposed that the general public do not know what pharmacy professionals do nor what role they have in the provision of safe and effective care and therefore questioned how assurance could be achieved. Respondents highlighted the need to raise awareness of the pharmacy profession as a whole. Similarly, there were many comments regarding the lack of public awareness of the existing CPD requirements and that this would not change with the new framework. For these respondents, there would be no impact on the public's perception and therefore no further assurance. Respondents suggested that

greater assurance to service users was dependent on public engagement and communications and that the proposed changes would need to be promoted effectively to achieve their aim of providing such assurances. It was these issues that account for the lower levels of agreement rather than greater concern about the validity or effectiveness of the proposals from the perspective of service users.

7. Impact of the new approach

The second part of the consultation survey focused on the possible impact of the new approach on three groups: people using pharmacy services, pharmacy professionals and employers. Questions were asked about the expected impact of the proposed changes on a five-point Likert scale from mostly positive to mostly negative and views were sought on what the nature of that impact would be.

7.1. Impact on pharmacy service users

	Individuals	%	Organisations	%
No impact	687	39%	16	23%
Mostly positive	640	36%	38	55%
Partly positive	241	12%	12	17%
Positive and negative	136	8%	3	4%
Partly negative	31	2%	-	N/A
Mostly negative	39	2%	-	N/A
Total	1774		69	

7.1.1. 48% of individuals and 72% of organisations described the changes as having a mostly positive or partly positive impact on service users. These respondents described the proposals as providing assurance that pharmacy professionals are carrying out regular activities to keep their knowledge and skills up to date which is beneficial to service users. Similarly, the focus on the standards for pharmacy professionals was seen to embed professionalism in service provision and the need to reflect on the benefits for patients would have a positive impact on service users by ensuring services are patient focussed. Furthermore, streamlining and simplifying the processes would allow pharmacy professionals more time to focus on patient outcomes. Other benefits to service users included improved practice, better services, and better counselling. Some commented that the impact on service users would not be seen immediately but that over time, the framework would enhance service provision.

7.1.2. Organisations were broadly more positive about the impact on service users than individuals. This was partly due to the fact that a larger proportion of individual respondents believed the new framework would have no impact on service users (39% of individuals compared with 23% of organisations). Those who felt there would be no impact highlighted the lack of awareness of what pharmacy professionals do and of the requirements for revalidation. In these cases, this lack of awareness meant service users would not see any marked impact from the proposed changes. Others stated that pharmacy professionals already provide a high standard of service and that the proposed changes will not affect this. It was apparent in the analysis that respondent selected the 'no impact' category when they felt the impact was in fact unknown. Many comments were made by both individuals and organisations that

it was difficult to qualify and quantify the impact and that there would need to be further evaluation to establish what would be the full impact of the proposals. There were requests for regular evaluation in order to track and evidence changes in practice that benefit service users.

- 7.1.3. Smaller numbers identified both positive and negative impact on service users (8% of individuals and 4% of organisations) and a very small number of individuals felt the overall impact would be partly or mostly negative. No organisations described only a negative impact. The negative comments focussed on concerns that the time taken to meet the requirements for revalidation would take pharmacy professionals away from service delivery and would therefore reduce the quality of services. This links to the resource implications of the proposed changes and individuals described themselves as being already over-burdened and wanting to focus on service delivery and patients rather than completing and recording CPD.

7.2. Impact on pharmacy professionals

	Individuals	%	Organisations	%
No impact	74	4%	2	3%
Mostly positive	686	39%	45	64%
Partly positive	191	11%	8	11%
Positive and negative	481	27%	9	13%
Partly negative	135	8%	3	4%
Mostly negative	205	12%	3	4%
Total	1772		70	

- 7.2.1. 50% of individuals and 75% of organisations agreed that there would be a mostly positive or partly positive impact on pharmacy professionals. This represented slightly more than the number rating the impact on service users and employers as positive. Conversely 20% of individuals and 8% of organisations identified only negative impact on pharmacy professionals. Very few respondents saw the changes as having no impact on pharmacy professionals (only 4% of individuals and 3% of organisations) and a considerable number of individuals and organisations saw both positive and negative outcomes (27% and 13% respectively).
- 7.2.2. Those with positive ratings described numerous benefits for pharmacy professionals including the increased flexibility in how registrants complete their revalidation and better alignment with their own scope of practice. The emphasis on reflection would enable pharmacy professionals to identify areas for development and enhanced feedback would help them to improve in their practice. As a result some respondents commented that the new framework will increase their self-awareness and confidence in their work, especially for those sampled for review. Others commented that the more streamlined process would benefit pharmacy professionals and described the new requirements as more engaging and meaningful. The peer discussion was cited as reducing the professional isolation felt by many, especially for certain groups such as locums, community pharmacists and some non-patient facing roles such as those working in consultancy.

- 7.2.3. Negative comments fell into two categories, those describing the negative impact on the profession as a whole and those identifying negative impact on certain groups. The general negative comments echoed the themes identified in the commentary under section 6 with a particular emphasis on the resource implications and the additional burden that the new framework may bring.
- 7.2.4. When referring to certain groups, respondents indicated that there would be a negative impact on individuals who may find it difficult to meet the requirements. This included locums for whom access to an appropriate peer was seen as a challenge. In addition, locums may have difficulties demonstrating how their work has impacted on patients due to the changing locations and patient groups they work with. There was similar concern regarding those in non-patient facing roles with feedback suggesting that the proposals lacked sufficient flexibility to enable these individuals to complete CPD relevant to their role. Pharmacy professionals in remote locations or isolated roles were also seen to be disadvantaged due to the new requirements for a peer discussion to take place. Questions were also raised about how registrants living and working overseas would meet the requirements. Respondents requested additional guidance for those in different sectors and different roles to help support these registrants.
- 7.2.5. Some respondents commented that the proposals placed a disproportionate burden on part-time workers by requiring them to do the same amount of professional development as their full-time colleagues. Other respondents suggested that the proposals would impact negatively on pharmacy professionals who were unemployed, between jobs or taking a career break as these individuals may find it challenging to complete their CPD, especially the peer discussion as they may not have direct access to any peers. More clarity and guidance was requested around the requirements for such situations. This linked to a wider theme around exemptions with suggestions that the reasons for not submitting should be extended to cover periods of unemployment, part-time work and caring or parental responsibilities. Some argued that annual submission meant these factors would have more impact on an individual's ability to complete all the requirements than the current system. There was a general lack of clarity around the process, eligibility and timelines for those unable to submit records and further guidance was requested.
- 7.2.6. There was general concern about the move towards a more reflective approach and how this would affect those less used to reflecting on their work. Pharmacy technicians were identified as a group who had little experience of reflective practice and would therefore need additional support and guidance to meet the requirements. Some respondents even suggested there should be a different revalidation process for each registrant group due to their different career paths. A small number of organisations asked for more research to be done on the impact of the proposals on pharmacy technicians as they were under-represented in the pilot study. Pharmacists towards the end of their careers were also referred to as a group who may struggle to adapt to the new requirements and some respondents expressed concern that it would result in people leaving the profession. It was suggested that more guidance and additional support should be made available for these registrants.

7.3. Impact on employers

	Individuals	%	Organisations	%
No impact	386	22%	7	10%
Mostly positive	556	31%	29	42%
Partly positive	186	10%	15	22%
Positive and negative	393	22%	10	14%
Partly negative	138	8%	5	7%
Mostly negative	113	6%	3	4%
Total	1772		69	

- 7.3.1. 41% of individuals and 64% of organisations described the impact on employers as mostly positive or partly positive. The reasons given included the fact that the new requirements will give employers further assurance that their employees are carrying out regular CPD and that their skills and knowledge are being kept up to date. Employers would benefit from improvements in practice and service delivery. There was also the suggestion that employers could link the revalidation requirements, especially the peer discussion, to internal quality monitoring and for identifying and addressing risk.
- 7.3.2. As with service users, some respondents said there would be no impact or the impact would be unknown (22% of individuals and 10% of organisations). For individuals, this was often due to the fact that CPD was seen as the responsibility of the individual and was often done during their own time. For others this was due to the fact that the possible impact on employers was not yet known and further evaluation is needed.
- 7.3.3. 14% of individuals and 11% of organisations identified a partly negative or mostly negative impact on employers. This was mostly due to the potential resource implications such as the additional time required for individuals to complete, record and submit their records. The requests for protected time for CPD would take pharmacy professionals away from their usual duties which could reduce service quality or may require employers to provide cover and backfill which would have cost implications. There was a lot of concern about the introduction of the peer discussion and how this would impact on employers. It could potentially involve the time of two members of staff and would therefore have a greater impact on resourcing. Respondents also commented on the need for employers to be more engaged with the process and to provide more support to employees in order for it to work effectively.
- 7.3.4. A considerable number saw both positive and negative impact of the proposals (22% of individuals and 14% of organisations). The reason given echoed those described above with these respondents agreeing employers would benefit from having assurance that their team were regularly updating their skills but would also have to invest more time and resources into providing support for their teams.

8. Equality impact

8.1. Impact on groups with protected characteristics

8.1.1. We are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to ensuring that our equality duties are met. The final question on the survey asked if there might be an impact of the proposals on individuals or groups who share protected characteristics.

	Individuals	%	Organisations	%
Yes	177	10%	10	15%
No	1567	90%	58	85%
Total	1744		68	

8.1.2. A small minority of both individuals (10%) and organisations (15%) indicated that they thought there would be an impact on groups who share protected characteristics. These included registrants with learning needs such as dyslexia, and registrants with disabilities that may make it difficult for them to complete the requirements in the formats requested. Different methods of recording and submission should be admissible such as verbal recordings and all guidance and materials must be made accessible for all. A small number of respondents highlighted the possible negative impact on those more likely to engage in part-time work such as women. There was also a number of respondents who identified age as a factor, suggesting older registrants may be less familiar with the concepts and therefore less inclined to engage. Additional support would be required for these individuals if necessary. Finally, more clarity was requested regarding the timelines for submission for registrants on maternity leave or for those with long term health issues.

9. About our individual respondents

A series of introductory questions sought information on individuals' general location, and in what capacity they were responding to the survey. For pharmacy professionals, further questions were asked to identify whether they are pharmacists, pharmacy technicians or pharmacy owners, and where they usually work. These questions were asked to help understand the profile of respondents to the consultation.

9.1. Location

	All	%
England	1487	85%
Scotland	156	9%
Wales	69	4%
Northern Ireland	5	<1%
Other	23	1%
Total	1740	

9.1.1. The distribution of individual respondents across England, Scotland and Wales is broadly similar to the distribution of the UK population.

9.2. Type of respondent

	All	%
A member of the public	11	1%
A pharmacy professional	1706	96%
A pre-registration trainee	34	2%
A student	13	1%
Other	21	1%
Total	1785	

9.2.1. In terms of types of respondents, the vast majority of individual respondents identified themselves as pharmacy professionals (96%).

9.3. Pharmacy professionals: part of the register

	All	%
Pharmacist	1253	72%
Pharmacy technician	440	25%
Pharmacy owner	41	2%
Total	1734	

9.3.1. Among pharmacy professionals, the percentage of respondents from each professional was broadly in line with the total registrant numbers for each profession. The number identifying themselves as pharmacy owners is notably small (2%). However, this group had two potential routes to respond to this consultation: as individuals, and on behalf of organisations. Responses from organisations have been dealt with separately.

9.4. Pharmacy professionals: usual workplace

	All	%
Community pharmacy	736	43%
Hospital pharmacy	519	30%
Pharmaceutical industry	52	3%
Pharmacy education and training	77	5%
Primary care organisation	180	11%
Other	143	8%
Total	1707	

- 9.4.1. 43% of pharmacy professionals responding to the survey identified community pharmacy as their usual workplace, 30% of respondents work in hospital pharmacy and 11% in a primary care organisation. The remainder work in other locations.

10. Monitoring questions

- 10.1.1. Data was collected on respondents' protected characteristics, as defined within the Equality Act 2010. The GPhC's equalities monitoring form was used to collect this information, using categories that are aligned with the census, or other good practice (for example on the monitoring of sexual orientation). The monitoring questions were not linked to the consultation questions and were asked to help understand the profile of respondents to the consultation, to provide assurance that a broad cross section of the population had been included in the consultation exercise. A separate equality impact assessment has been carried out and will be published alongside this analysis report.

Appendix 1: Organisations

The following organisations engaged in the consultation through the online survey, email responses and one-to-one meetings:

Age UK

APTUK Yorkshire and Humber Branch

Association of Independent Healthcare Organisations (AIHO)

Association of Independent Pharmacies

Association of Pharmacy Technicians UK (APTUK)

Avon Local Pharmaceutical Committee

Bexley, Bromley and Greenwich Local Pharmaceutical Committee

Boots

Boots Pharmacists' Association

BPSA

Buchanhaven Pharmacy

Cambridge University Hospitals NHS Foundation Trust

Care Inspectorate

Care UK

Celesio UK

Central and North West London NHS Foundation Trust

Chief Pharmacists Group in Wales (CPGW)

City and Hackney LPC

Co Durham and Darlington Local Pharmaceutical Committee

Community Pharmacists Wales (CPW)

Community Pharmacy Scotland

Company Chemists' Association

Coventry LPC

Directors of Pharmacy Scotland

Dudley Taylor Pharmacies Ltd

East Sussex Local Pharmaceutical Committee

Education and Training Operational Sub-Group of the All Wales Chief Pharmacist Committee

Essex Partnership University NHS Foundation Trust

Everetts Pharmacy
General Medical Council (GMC)
Guild of Healthcare Pharmacists
Health Education England - London and South East Pharmacy Workforce Group
Health Education England (HEE)
Health education England Thames Valley
Health Education London and South East Pharmacy Team
Healthwatch
Healthwatch Barnsley
Healthwatch Southend
Hertfordshire Local Pharmaceutical Committee
Hightown Pharmacy
Humber Local Pharmaceutical Committee
Kent Local Pharmaceutical Committee
King Edward VII Hospital
Lambeth Southwark and Lewisham LPC
Lindsay and Gilmour
Medacs Healthcare
Merton Sutton & Wandsworth Local Pharmaceutical Committee
National Association of Women Pharmacists
National Pharmacy Association
NHS Education for Scotland
NHS Highland Area Pharmaceutical Committee
NHS Pharmaceutical Technician Specialists Education and Training Group (TSET)
NHSE Specialist Pharmacy Service
NHSGGC Area Pharmaceutical Committee
North East and North Cumbria Clinical Pharmacy Network
Oxford Health NHS Foundation Trust
Patients Association
Pharmaceutical Services Negotiating Committee (PSNC)
Pharmacist Support

Pharmacists' Defence Association (PDA)
Pharmacy Forum NI (PSNI)
Pharmacy London
Primary and Community Healthcare Pharmacy Network (PCCPN)
Professional Standards Authority (PSA)
Rowlands Pharmacy
Royal College of General Practitioners (RCGP)
Royal College of Surgeons and Physicians Glasgow (RCPSG)
Royal Pharmaceutical Society (RPS)
RPS Consultant Pharmacist Group
RPS London North West Local Practice Forum
Scottish Health Council
Sheffield Children's NHS Foundation Trust
South Staffordshire Local Pharmaceutical Committee
STAR Medication Consultants Ltd
The Centre for Professional Development and Lifelong Learning, Keele University
The Royal Marsden NHS Trust
UK Clinical Pharmacy Association (UKCPA)
University Hospitals of Leicester
University of Manchester
Vida Rogers Ltd
Wales Centre for Pharmacy Professional Education, Cardiff University
Weldricks Pharmacy
Welsh Pharmaceutical Committee

Appendix 2: Consultation questions

The revalidation framework: process

The revalidation framework sets out our proposals for carrying out, recording and submitting continuing professional development entries.

It covers the following areas:

- your records – recorded CPD, a peer discussion and a written reflective account
 - submitting records to us and what happens when they are not, or cannot be, submitted
 - selecting records for review
 - reviewing records and feedback
 - how we follow up if the review criteria are not met
1. Do you have any comments on any of the steps in the process covered in the framework?

The framework aims to provide further assurance to the public that pharmacy professionals keep their knowledge and skills up to date and remain fit to practise throughout their careers. The changes we are proposing are:

- a simplified approach to CPD recording
 - introducing a peer discussion, and
 - introducing a reflective account based on the standards for pharmacy professionals
2. Do you think the changes above will help to support registrants in their practice and provide assurance that pharmacy professionals remain fit to practise?
 3. Do you have any comments about the changes we have proposed?
 4. Do you think the revalidation framework overall will achieve its aim of providing further assurance to users of pharmacy services?
 5. Is there anything else, not covered in the framework, that you would find useful? Please give details.

Revalidation framework: impact

6. What kind of impact do you think the proposals will have on people using pharmacy services?
7. What kind of impact do you think the proposals will have on pharmacy professionals?
8. What kind of impact do you think the proposals will have on pharmacy employers?
9. Please give any further comments you have on the possible impact of the proposals on any of the above groups.

Equality analysis

10. Do you think the proposal might have an impact on certain individuals or groups who share any of the protected characteristics? If 'Yes', please explain and give examples.

Meeting paper

Council meeting on Thursday, 12 October 2017

Public business

Engagement and communications report

Purpose

To keep 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 in the last quarter and highlights upcoming events and activities.

2. Consultation on ensuring a safe and effective pharmacy team

- 2.1 Our consultation on guidance to ensure a safe and effective pharmacy team was open from 20 July 2017 to 11 October 2017.
- 2.2 On the day of launch, we sent targeted emails to; registrants, training providers, awarding bodies, superintendent pharmacists, organisations representing patients and the public and a range of other stakeholders to announce the launch of the consultation and encourage responses.
- 2.3 We have also promoted the consultation through an article and blog in Regulate, our social media platforms and a press release, which resulted in media coverage across the pharmacy trade press
- 2.4 Over 1700 people have so far visited the landing page for the consultation on our website. This landing page includes a link to a resource 'toolkit' which included pre-written tweets and links to relevant webpages, an FAQ and pre-written news story to help stakeholders to notify their audiences about the launch. A range of organisations, including local Healthwatch and pharmacy organisations, have used these resources to promote the consultation to their members
- 2.5 We have also engaged with stakeholders at a range of events, including; three focus groups with patients and the public in London, Glasgow and Cardiff, three roundtables with training providers, awarding bodies and

pharmacy stakeholders, and presentations and discussions at the Pharmacy Show, the Association of Independent Multiple Pharmacies' Superintendents' Forum and several local LPC events.

- 2.6 We identified that unregistered staff would be a challenging group to engage in the consultation, with this group being less likely than other groups to complete the full consultation survey. We therefore created a short survey that could be completed within 5 minutes and asked employers and training providers of unregistered staff to encourage their employees and trainees to complete the survey. We also asked unregistered staff visiting our stand at the Pharmacy Show to complete the short survey on iPads.

3. New standards for the initial education and training of pharmacy technicians

- 3.1 The new standards for the initial education and training of pharmacy technicians were published on 3 October, after being approved by Council at its September meeting.
- 3.2 We have highlighted the publication of the final standards to all key stakeholders through targeted emails, media coverage and our social media channels, and encouraged stakeholders to give their feedback on the draft evidence framework which has been published on our website.
- 3.3 We will continue to support the Education team to reach out through key networks to course designers and providers, education and training leads, employers and professionals to explain the implications of the new standards.

4. Joint statement on conflicts of interest

- 4.1 The General Pharmaceutical Council and the other eight regulators of health and care professionals have signed a joint statement, which sets out what is expected of all healthcare professionals in relation to avoiding, declaring and managing conflicts of interest across all healthcare settings.
- 4.2 The statement is intended to support each regulator's professional standards, codes and guidance. In addition to the joint statement, we, alongside the other regulators, have published case studies. The case studies illustrate the principles in the statement, and give examples of how health professionals should deal with situations where a conflict of interest might arise.
- 4.3 We have promoted the joint statement through a press release (which resulted in coverage across the pharmacy trade media), an article in Regulate (which has been viewed over 1600 times) and through our social media channels.

5. Responding to external developments

- 5.1 We have issued statements welcoming two key developments within pharmacy. In our statement welcoming the publication of *Achieving Excellence in Pharmaceutical Care*, the Scottish Government's strategy for pharmacy, we expressed our commitment to continuing our work with the Scottish government to achieve our shared ambition to further improve the quality of pharmaceutical care in Scotland. In our statement responding to the Secretary of State for Health's announcement of a new initiative focused on

reducing prescribing and medication errors, we said we look forward to learning how our work with the pharmacy professions and other regulators can complement this initiative.

6. Recent events and meetings

- 6.1 We exhibited at the RPS conference from 3-4 September and the Pharmacy Show from 8-9 October, with these key events in the pharmacy calendar giving us the opportunity to engage directly with registrants and answer their queries about our work. At the RPS conference, Nigel gave a presentation about the future of revalidation. At the Pharmacy Show, Nigel took part in a panel session about the rebalancing programme and Duncan led two sessions in the keynote theatre; one on revalidation and one on quality, standards and the pharmacy team.
- 6.2 Listed in Appendix 1 is a non-exhaustive selection of significant events and meetings held since April 2017.
- 6.3 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.

7. Upcoming events and activities

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

Visits to meet MPharm students, pre-registration pharmacist trainees and early-years pharmacists and pharmacy technicians

**1. Visit to Whittington Hospital, Archway, London
10:30-13:30, 16 October 2017**

- An opportunity for Council members to meet early years pharmacists and pre-registration trainees working in clinical and domiciliary settings at the Whittington Hospital in Archway

**2. Visit to University of East Anglia
11:00-14:00, 21 November 2017**

This visit will include:

- a tour of the school
- a discussion with staff about the structure of the 4-yr MPharm degree and integration within it
- a discussion with staff about the UEA 5-yr MPharm degree

**3. Visit to University of Central Lancashire
09:00- 16:00, 22 November 2017**

This visit will include:

- observation of Inter-Professional Education Chaos day
- a tour of the school
- a presentation about Comensus (patient involvement programme) Discussion with 3-4 patients involved in the MPharm
- discussion with staff about the MPharm degree, focusing on patient involvement
- Discussion with a small group of patients who are involved in the UCLAN MPharm

**4. Visit to a GP Practice in Ealing
11:00-13:00, 13 December 2017**

- This visit will involve meeting pharmacists and pharmacy technicians embedded in a GP practice

Other events and activities:

Defence Medical Services Pharmacy Conference, 26/10/17, 11:00-11:45

Lichfield, Staffordshire

Osama will give a presentation on key developments within pharmacy regulation

Annual Regulation Conference, 30/10/17

Edinburgh

Duncan Rudkin will join a panel to discuss responsive regulation and Osama will be giving a presentation about revalidation

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

Leicester

Osama Ammar will 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 will be leading a discussion about revalidation

APTUK North Merseyside Branch Meeting, 23/11/17

Liverpool

Osama will be presenting on key updates in pharmacy regulation, including revalidation

Cheltenham and Gloucester Local Pharmaceutical Committee Meeting, 29/11/17

Cheltenham

Osama will be presenting on key updates in pharmacy regulation, including revalidation

RPS Wales Medicines Safety Conference, 29/11/17

Cardiff

Darren and colleagues from the Comms Team will be updating delegates on key developments within pharmacy regulation

8. Consultations

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

9. Equality and diversity implications

9.1 We continue to work to improve the accessibility and inclusiveness of 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. Recent support we have provided has included helping a participant to find mobility scooter hire near the event venue, and supporting a participant with dementia by discussing their communication needs with them.

Recommendations

The Council is asked to note this paper

Rachael Oliver, Head of Communications
General Pharmaceutical Council

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5 October 2017

Events

1. Consultation on guidance to ensure a safe and effective pharmacy team

- Patient focus group, London (06/09/17)
- Patient focus group, Glasgow (11/09/17)
- Dudley Local Pharmaceutical Committee AGM (11/09/17)
- Patient focus group, Cardiff (13/09/17)
- Roundtable with training providers (14/09/17)
- Leicester Local Pharmaceutical Committee AGM (18/09/17)
- NPA Practice and Policy committee meeting (19/09/17)
- Roundtable with stakeholders (19/09/17)
- Roundtable with awarding bodies (20/09/17)
- AIMP Superintendents Forum (09/10/17)
- Pharmacy Show presentation (09/10/17)

List of meetings:

Listed below is a non-exhaustive selection of significant meetings held during the two months since the last Chief Executive and Registrar's report to Council.

Chair (Nigel Clarke):

- Meeting with Postgraduate Pharmacy Dean, NHS Education for Scotland (with LC)
- Meeting with Chief Pharmaceutical Officer Scotland (with LC)
- Meeting with Head of Pharmacy, Head of Pharmacy Development and Regulation and Head of Pharmacy Practice and Drug Reimbursement, Department of Health (with DR)
- Meeting with Chief Executive, Pharmaceutical Society of Northern Ireland (with DR)
- Meeting with Chair, GPhC Appointments Committee
- Royal Pharmaceutical Society Annual Conference – speaking
- Meeting with Chief Executive, Royal Pharmaceutical Society (with DR)
- Meeting with President, Royal Pharmaceutical Society
- Pharmacy and Public Health Forum meeting
- Pharmacy Business Awards
- Pharmacy Show - panel session

Staff:

- Meeting with Head of Pharmacy, Head of Pharmacy Development and Regulation and Head of Pharmacy Practice and Drug Reimbursement, Department of Health (DR with NC)
- CQC Regulation of GP Programme Board Meeting (CBS)
- Meeting with Andrew Evans, CPhO for Wales (DH)
- Pharmacy Schools Council Meeting (HS)
- Chief Executives Steering Group (MF)
- Meeting with RPS Scotland (MF, LC)
- Meeting with RPS Director for Wales (DH)
- Meeting with Associate Head of Pharmacy, Health Education England (HS)
- Meeting with President, Association of Pharmacy Technicians UK (HS)
- Meet with Wales' Chief Pharmacists Peer Group (DH & C B-S)
- Meeting with Chief Executive, Pharmaceutical Society of Northern Ireland (DR with NC)
- Meeting with Programme Director, Integrated Pharmacy Across Care Settings (IPACS), NHS Digital (CBS, HS)
- CQC National Cross Regulatory meeting (CBS)
- Meeting with Chief Pharmaceutical Officer England (HS)
- Meeting with Chief Operating Officer and Assistant General Secretary, Pharmacists Defence Association (CBS)
- Pharmacy Assurance Programme Board meeting (HS)
- Meeting with Chief Pharmaceutical Officer England (DR)
- Health and Care Innovation Expo (CBS)
- President, Vice President and Graduate Officer, British Pharmaceutical Students Association (DR, MF)
- Fitness to Practise Directors meeting (CBS)
- Chief Executives Steering Group meeting (DR)
- Community Pharmacy Scotland Dinner (DR, LC)
- Meeting with Chief Pharmaceutical Officer Scotland (DR, LC)
- Meeting with Deputy Director – Professional Regulation and Briefing Manager, Department of Health (DR, MF)
- Meeting with Chief Executive, Royal Pharmaceutical Society (DR with NC)
- Chief Executives Legislation Group Meeting (DR)
- Health and Social Care Regulators Forum meeting (DR)
- Pharmacy Business Conference (DR)
- NPA Conference & Dinner (DR)
- Pharmacy Show (DR, MF with NC)
- CQC State of Care 16/17 Report Launch (DR)
- Meeting with Chief Executive, Community Pharmacy Scotland (LC)
- Disclosure Scotland Advisory Stakeholder Advisory Board (LC)
- Meeting with Healthcare Inspectorate Wales (DH)

Appendix 2

Active and new consultations

Title	Organisation	Summary	Deadline	Response	Reasons / Considerations
<p>Safe and Effective Staffing in Health and Social Care</p> <p>http://www.gov.scot/Publications/2017/04/1188</p>	<p>Scottish Government</p>	<p>This consultation focused on proposals to enshrine safe staffing in law, starting with the nursing and midwifery workload and workforce planning tools. This would require organisations providing health and social care to apply nationally agreed, evidenced-based workload, and workforce planning methodologies and tools, and ensure that key principles, notably consideration of professional judgement, local context and quality measures, underpin workload and workforce planning and inform staffing decisions.</p>	<p>05/07/2017</p>	<p>Reviewed by Lynsey Cleland Decision not to respond.</p>	<p>This topic does not relate directly to our role or core functions as it focuses on nursing and midwifery. However, we will consider any findings that are extended to safe and effective staffing in pharmacy.</p>
<p>A new equivalence route to register for public health specialists: retrospective portfolio route</p> <p>https://www.ukphr.org/2017-2/</p>	<p>UK Public Health Register</p>	<p>The UK Public Health Register is an independent, regulator for public health professionals in the UK, particularly for those public health professionals who have no other regulatory body. The consultation sought views on a draft new equivalence route to registration for public health specialists by way of retrospective portfolio assessment and the draft framework.</p>	<p>07/07/2017</p>	<p>Reviewed by the Education Team. Decision not to respond.</p>	<p>It is not usually appropriate for the GPhC to respond to a consultation from another independent statutory health professional regulator.</p>
<p>Consultation on a review of the Standards of Good Regulation</p>	<p>PSA</p>	<p>The consultation outlined how the PSA could approach reviewing the standards and invited responses on how this review should go ahead. In</p>	<p>12/09/2017</p>	<p>Reviewed by Laura McClintock. <u>Response available here</u></p>	

http://www.professionalstandards.org.uk/what-we-do/improving-regulation/consultation		<p>particular, the PSA sought views on whether improvements to the standards would be achieved by making modifications, or whether there might be value in exploring a different approach altogether and creating a new system based around principles rather than regulatory functions.</p>			
<p>Post-implementation Review of the Human Medicines Regulations 2012</p> <p>https://www.gov.uk/government/consultations/consultation-on-the-post-implementation-review-of-the-human-medicines-regulations-2012-mlx-391</p>	MHRA	<p>MHRA are reviewing the impact of the Human Medicines Regulations 2012. This is part of a wider exercise within government to test the impact of legislation five years after implementation. The main focus of the consultation was the impact of the regulations on certain groups, as well as questions about the costs, benefits and any unintended consequences.</p>	06/07/2017	<p>Reviewed by Laura McClintock and Ambrose Paschalides. Decision to respond informally.</p>	<p>Given the specific areas covered in the consultation, we were unable to provide useful feedback. However, we offered to discuss the issues more generally with the MHRA.</p>
<p>Departmental Review of Regulatory Policy and Legislation</p>	Department of Health Northern Ireland	<p>The Department's current regulatory policy dates back to Best practice – Best care: improvement and monitoring of HSC services in 2001. They are now carrying out a review of regulatory policy and legislation, and are seeking engagement and contributions to the development of the policy and subsequent consultation document.</p>	07/07/2017	<p>Reviewed by Sarah Jennings Decision to respond informally.</p>	<p>We did not provide a formal response to this consultation. However, we offered to meet to share our experiences of regulation as well as our thinking on the future of regulation. There will be a more formal consultation after the summer, which we will also review.</p>
<p>Professional standards for pharmacy services: an updated draft for consultation July 2017</p> <p>https://www.rpharms.com/making-a-difference/projects-and-campaigns/hospital-standards-update</p>	RPS	<p>The professional standards describe quality pharmacy services and provide a broad framework to support pharmacists and their teams to develop their professional practice, continually improve services, shape future services and roles, and deliver high quality patient care across all settings. The professional standards help to support a culture of openness, transparency and candour that puts patients first through encouraging professionalism.</p>	11/09/2017	<p>Reviewed by the Policy and Standards Team. Decision to respond informally.</p>	<p>We did not provide a formal response. However, this was discussed during regular meeting between the policy leads at the RPS and GPhC.</p>

<p>Items which should not routinely be prescribed in primary care</p> <p>https://www.engage.england.nhs.uk/consultation/items-routinely-prescribed/</p>	NHSE	The objective of this work is to support CCGs in their decision-making, to address unwarranted variation and to provide clear national advice to make local prescribing practices more effective.	21/10/2017	Reviewed by Sarah Jennings and the Policy and Standards Team. Decision not to respond.	The topic does not relate directly to our role or core functions and it is not appropriate for us to comment on items which can be prescribed.
<p>Services Fit for the Future, a White Paper</p> <p>https://consultations.gov.wales/consultations/services-fit-future</p>	Welsh Government	The White Paper contains a number of proposals relating to quality and governance in health and care in Wales.	29/09/2017	Reviewed by Darren Hughes. Response available here	
<p>Consultation on the development of a data standard for a care and support plan</p> <p>http://theprsb.org/news/2017-08/70-digital-care-and-support-planning-survey-now-live</p>	Professional Record Standards Body (PRSB)	The Professional Record Standards Body (PRSB) has been commissioned to identify the standards required for a digital care and support plan. The project is being run in conjunction with North West London Collaboration of Clinical Commissioning Groups (NWL CCGs) and NHS Digital. This consultation seeks views from patients, carers, health and care professionals and industry representatives on the content of a standard for a digital care and support plan.	04/09/2017	Reviewed by Laura McClintock and Sarah Jennings. Decision not to respond.	It was not appropriate for the GPhC to respond as it does not relate directly to our role and core functions, nor does it have a direct impact upon our strategic or corporate plans.
<p>Consultation on standards of proficiency for registered nurses</p> <p>https://www.nmc.org.uk/education/programme-of-change-for-education/programme-change-education/</p>	NMC	The consultation focused on the new draft standards of proficiency that should prepare the future registered nurse for safe and effective practice both now and into the future.	12/09/17	Reviewed by the Education Team and Policy and Standards Team. Decision not to respond.	It is not usually appropriate for the GPhC to respond to a consultation from another professional regulator. However, we will continue to keep up to date with any key developments within other healthcare professions that

					might be relevant to our own work.
<p>Consultation on education framework: standards for education and training</p> <p>https://www.nmc.org.uk/education/programme-of-change-for-education/programme-change-education/</p>	NMC	In addition to the work on new standards of proficiency, the NMC also sought views on the education and training standards which all approved education institutions (AEIs), practice placement and work based learning providers must meet in order to manage and deliver all NMC approved education programmes.	12/09/17	Reviewed by the Education Team and Policy and Standards Team. Decision to respond informally.	Members of the Education Team met with the NMC to discuss the consultation and developments in education more generally.
<p>Consultation on prescribing and standards for medicines management</p> <p>https://www.nmc.org.uk/news/press-releases/nmc-seeks-views-on-new-prescribing-and-medicines-management-proposals/</p>	NMC	This consultation focused on the work that the NMC has undertaken in the areas of nurse and midwife prescribing and management of medicines. They propose to adopt the Royal Pharmaceutical Society's Single competency framework for all prescribers as the new standards of proficiency for nurse and midwife prescribing practice. They also consulted on draft requirements for nurse and midwife prescribing programmes.	14/09/17	Reviewed by the Education Team and Policy and Standards Team. Decision to respond informally.	Members of the Education Team met with the NMC to discuss prescribing standards development.
<p>Consultation 2 Our next phase of regulation</p> <p>http://www.cqc.org.uk/get-involved/consultations/our-next-phase-regulation-consultation-2</p>	CQC	This was the second consultation on proposed changes to the way that the CQC regulates health and adult social care services. This included proposals to regulate primary medical services and adult social care services, improve the structure of registration, and clarify the definition of registered providers.	08/08/2017	Reviewed by the Policy and Standards Team. Decision not to respond.	It was not appropriate for the GPhC to respond as it does not relate directly to our role and core functions, nor does it have a direct impact upon our strategic or corporate plans.
<p>Consensual disposal of fitness to practise cases</p> <p>https://www.optical.org/en/get-involved/consultations/</p>	GOC	Consensual disposal is a case management tool that GOC will use to identify and process fitness to practise cases, which may be suitable for concluding without a contested hearing.	20/09/2017	Reviewed by the Policy and Standards Team, and Fitness to Practise. Decision not to respond.	It is not usually appropriate for the GPhC to respond to a consultation from another professional regulator. However, we will continue to keep up to date with any key developments within other healthcare professions that might be relevant to our own

					work, including areas relating to the future of fitness to practise.
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Meeting paper

Council on Thursday, 12 October 2017

Public business

Professional Standards Authority (PSA) annual performance review

Purpose

To update Council on the Professional Standards Authority (PSA) performance review process

Recommendations

Council is asked to note this paper and the outcome of the 2016/17 performance review

1. Introduction

- 1.1. The Professional Standards Authority (PSA) published its annual performance review report on the GPhC for 2016/17 on 29 September 2017.
- 1.2. The review concluded that the GPhC had met all of the standards of good regulation for 2016/17.

2. The performance review: key findings

- 2.1 The PSA assesses the performance of the nine health and care professional regulators against its standards of good regulation, which cover the following areas: guidance and standards; education and training; registration; and, fitness to practise.
- 2.2 During March 2017, the PSA carried out an initial review of our performance from 1 April 2016 to 28 February 2017. This included an analysis of policy, guidance and consultation documents, council papers, statistical datasets and checks of our register. Following this assessment, the PSA carried out a targeted review of our performance against Standard 2 of Education and Training, Standard 3 for Registration, and Standards 3, 4, 5 and 6 for Fitness to Practise.
- 2.3 The PSA sought and obtained further information as part of the targeted review, and after carrying out a detailed analysis, concluded that the GPhC met all of the standards. The performance report highlighted a number of activities and initiatives that demonstrated how we were meeting the standards, including:
 - Maintaining our performance in terms of progressing fitness to practise cases, with no appeals against fitness to practise decisions via the PSA's Section 29 powers, or other concerns about our decision-making in fitness to practise cases.

- Carrying out wide-ranging engagement on the new standards for pharmacy professionals, including an additional consultation on religion, personal values and beliefs, which the PSA described as an example of good practice in consulting and decision-making.
- Consulting on initial education and training (IET) standards for pharmacy technicians, as well as revalidation proposals for pharmacy professionals.
- Introducing a mechanism that allows students to raise concerns about pharmacy education and training directly with the GPhC, and creating a webpage, online concerns form and supporting materials.
- Acting on a number of recommendations from the audit of our work on interim accreditation events, including revising our guidance for providers to make the purpose of interim accreditation events more explicit, and to provide additional guidance around the process and what to expect.
- Acting on a number of recommendations from the integrity of the register audit, including a full review of our process for updating the register, incorporating an investigation of a small number of untimely updates.
- Continuing to analyse and enhance our understanding of candidate performances and the differences between different groups of candidates.

2.4 The report highlighted our work in relation to revised threshold criteria and noted how the existing criteria will be used alongside the new standards for pharmacy professionals until the revised criteria is implemented in January 2018. The PSA confirmed that they had no concerns about this approach overall, but made it clear that they will continue to monitor the impact of the revised criteria going forward.

2.5 Additionally, the report looked at the impact of the revised Investigating Committee (IC) guidance, which was considered in last year's performance report. This further review provided the necessary reassurance to the PSA that cases closed at IC stage (where the realistic prospect test was met) were not resulting in unduly lenient outcomes.

3. Equality and diversity implications

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

4. Communications

4.1 The PSA published the performance review report on 29 September 2017. We have also published the report on the GPhC website, along with a supporting press release. We will continue to report to Council on progress and performance throughout the year; those reports are available to the public through our website.

5. Resource implications

5.1 The PSA is funded for its performance review activities through a levy imposed on all the health and care professional regulators it oversees, and launched a consultation on the 2017/18 levy on 22 September 2017.

5.2 Following the consultation, the PSA will be required to submit their 'Statement of Needs' to the Privy Council on 17 November 2017. This is to provide the Department of Health/Privy Council appropriate time to determine the fees before the end of February 2018. The PSA have indicated that they are not planning any changes to their activities and are continuing to restrain those costs that are within their control as much as possible.

6. Risk implications

- 6.1 There are risks for the GPhC if it fails to respond adequately to the PSA recommendations and observations. We have effective arrangements in place to ensure we are monitoring progress and performance in all areas covered by the PSA standards of good regulation.

7. Monitoring and review

- 7.1 The PSA continues to monitor the GPhC, and other health and care regulators, throughout the year and reports the outcome of reviews to the UK Parliament on an annual basis.
- 7.2 We will continue to review the reports of other regulators as and when these are published by the PSA throughout the performance review cycle. This will enable us to identify any other areas of good practice and learning that may be relevant to our own work.
- 7.3 As to the future of the performance review process, Council is aware that we recently responded to the PSA's consultation, which looks at whether improvements to the standards of good regulation could be achieved by making modifications, or whether there might be value in exploring a different approach altogether and creating a new system based around principles rather than regulatory functions.
- 7.4 The feedback from the consultation has not yet been published. However, we understand that the analysis will inform a second public consultation paper on revised standards, which is due to take place towards the end of 2017. The PSA have advised that they intend to settle final proposals in early 2018 for adoption in the performance review cycle beginning in 2019.

Recommendations

Council is asked to note this paper and the outcome of the 2016/17 performance review.

Laura McClintock, Chief of Staff

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Meeting paper

Council 12 October 2017

Type of business

General Data Protection Regulation

Purpose

To update council on changes to data protection legislation, effective from 25 May 2018

Recommendations

The council is asked to note its role in supporting the work of the Data Protection Officer in implementing changes and in enabling the GPhC to comply with the new legislation on an ongoing basis.

1. Introduction

- 1.1. The General Data Protection Regulation (GDPR) was developed by the EU to update the 1995 directive to reflect the challenges caused by technological developments and globalisation over the last 20 years. As a regulation, rather than a directive, it also aims to provide greater consistency to the protection of European citizens' personal data, wherever it is held.
- 1.2. Many of the fundamental principles of the GDPR remain the same as the Data Protection Act 1998 (DPA) and the Information Commissioner's Office (ICO), the regulator for data protection legislation, has described the GDPR as 'an evolution, not a revolution'¹. However, there are some key changes, which will be the focus of this paper.
- 1.3. The UK government has stated that the UK's decision to leave the EU will not affect the GDPR's commencement in the UK. The first reading of the Data Protection Bill was given in the House of Lords on 13 September and the second reading will be on 10 October.

2. GDPR implications

2.1 Data protection officer

- 2.1.1. The GDPR requires public authorities to have a designated data protection officer (DPO), who reports to the highest management level. The GPhC has previously designated this role to the Head of Governance and Facilities, who reports to the Chief Executive and Registrar.
- 2.1.2. Much of the role of the DPO is similar to now, but the tasks become mandatory. They include:
 - Advising on data protection issues

¹ [Deputy Information Commissioner's blog, August 2017](#)

- Monitoring compliance with legislation
- Acting as a point of contact for members of the public and the ICO
- Raising awareness and providing training
- Considering data protection risks and advising on data protection impact assessments

2.1.3. The GPhC has new obligations and must:

- involve the DPO in a timely manner in all issues relating to data protection
- provide support and resources for the DPO to carry out his mandatory tasks
- not instruct the DPO – the role must be independent

2.1.4. Council has an important role to play in supporting the DPO and making sure that his advice is listened to, that risks are managed effectively, and that the DPO's independence is maintained. It is proposed that the DPO will refer matters to Council if he has serious concerns about the GPhC's data protection practice.

2.2 Accountability and governance

2.2.1. The principles for processing personal data are familiar from the DPA but there is an additional principle of accountability. This means that organisations must show how they comply with the principles, for example, by documenting decisions about data processing activities and their reasons for processing data.

2.2.2. This principle complements the requirement for transparency. Organisations must tell individuals how they are processing their data. The GPhC usually does this through its privacy policy and privacy notices on forms when we collect data. These will be updated to meet new requirements and we are developing 'just in time' notices in new electronic forms. We are also reviewing the publication and disclosure policy.

2.2.3. The GDPR requires organisations to put in place comprehensive but proportionate governance measures and uses the principle of 'privacy by design and default'. These measures include data protection impact assessments (DPIAs), which become mandatory for certain types of higher risk processing. DPIAs are risk assessments that specifically focus on data protection questions. Our policy now requires a DPIA to be carried out for all new projects involving personal data.

2.3 Rights of individuals

2.3.1. The GDPR strengthens some of the rights of individuals that exist in the DPA and adds some new ones. The 'right to be forgotten' has been prominent in the news. This allows individuals to ask for their data to be removed if there is no compelling reason for the organisation to continue processing it. It is not an absolute right and an organisation does not have to agree if data is processed 'to meet a legal obligation or for the performance of a public interest task or exercise of official authority'.

2.3.2. There are some additional requirements in relation to subject access, when individuals can request copies of data we hold about them, or information about how we process their data. The time limit for responding reduces from 40 days to one month.

2.3.3. Rights in relation to automated decision making are strengthened and now specifically include profiling. An organisation using profiling technologies has to ensure processing is fair and transparent

by, among other things, providing meaningful information about the logic involved, the significance of the profiling and the envisaged consequences.

2.4 Suppliers and contracts

2.4.1. The GDPR makes suppliers or contractors, who process personal data on behalf of GPhC, responsible for data protection in their own right. This does not mean though, that we have no responsibilities ourselves.

2.4.2. The GPhC is expected to thoroughly assess the security practices of potential suppliers, have contracts with suppliers that meet the new requirements, and review their performance on an ongoing basis. The ICO is currently consulting on its guidance covering this aspect of the GDPR.

2.5 Breaches of the legislation

2.5.1 The GDPR introduces mandatory reporting of breaches to the ICO and affected individuals, where individuals are put at risk. There will be increased financial penalties of up to:

- €20m or 4% of turnover for a breach of data protection principles or data subjects' rights
- €10m or 2% of turnover for administrative failures, such as failure to report a breach or carry out data protection impact assessments

The ICO is currently able to fine up to £0.5m.

2.5.2 Organisations will be expected to notify the ICO quickly and within three days of discovering a breach, but are not expected to have fully investigated at this stage.

2.6 International data sharing

2.6.1. Britain's exit from the EU may have an impact on our ability to share information with regulators and other organisations in Europe, and their ability to share with us, as the EU will review whether the UK data protection framework remains 'adequate' for European countries to share data. We will monitor this as Brexit negotiations continue.

3. Equality and diversity implications

3.1 The GDPR references the Charter on fundamental rights of the European Union and says that everyone has the right to the protection of personal data concerning him or her.

3.2 We need to be prepared to offer copies of information that individuals are entitled to under subject access provisions in accessible formats.

3.3 The project to implement GDPR will undergo an Equality Impact Assessment.

4. Communications

4.1 Communications to staff will formally begin in the autumn. We have already started engaging with managers and staff working on new projects so that we capture the GDPR requirements in new systems and processes.

- 4.2 We are launching a new series of training presentations on information governance on the intranet in October. The data protection module will be refreshed in spring 2018 with the new GDPR requirements.
- 4.3 We will update privacy policies on our website and notices in forms in spring 2018 so that registrants and other stakeholders are aware of how we process their data.

5. Resource implications

- 5.1 The work to prepare for GDPR implementation will impact teams across the organisation. We are focussing on embedding the new requirements in new projects. The governance team will support this work and work with business teams to update their existing processes as required.
- 5.2 An additional governance team member with risk analysis expertise was recruited to support this work and ongoing work on risk management and information governance. We are likely to need contract support in 2018 to work on records management improvements.

6. Risk implications

- 6.1 The most significant risks are the financial and reputational risks if the GPhC breaches the legislation. We take IT security measures to protect against IT threats and will continue to improve organisational measures and continue with training and awareness-raising to make sure that staff are fully aware of their responsibilities.
- 6.2 We also need to manage supplier risks and make sure that we engage with suppliers on information security issues.
- 6.3 Specific risks will be addressed as part of the DPIA and risk assessment process.

Recommendations

The council is asked to note its role in supporting the work of the Data Protection Officer in implementing changes and in enabling the GPhC to comply with the new legislation on an ongoing basis.

Matthew Hayday, Head of Governance and Facilities

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3 October 2017

Meeting paper

Council 12 October 2017

Public business

Appointment of external auditors

Purpose

To appoint external auditors for the General Pharmaceutical Council

Recommendations

The Council is asked to:

- i. formally request the resignation of the previous external auditors, Grant Thornton
- ii. appoint, following the recommendation of the Audit and Risk Committee tender panel, Crowe, Clark & Whitehill as external auditors for a period of three years

1. Introduction

- 1.1 Under the Pharmacy Order 2010, Council members must prepare financial statements for each financial year. Under that law, the Privy Council has directed the GPhC to prepare the financial statements in accordance with United Kingdom Generally Accepted Accounting Practice (United Kingdom Accounting Standard and applicable laws) including Financial Reporting Standard 102. This requires that the Council appoint external auditors to provide assurance that the accounts provide a true and fair view of the state of affairs and the surplus or deficit of the GPhC for the reporting period.
- 1.2 In the Scheme of Delegation, Council has delegated authority for making recommendations about the appointment of auditors to the Audit and Risk Committee (ARC). This paper sets out the process the committee used to procure external audit services and recommends that the Council appoints the successful service provider.

2. Tender Process

- 2.1 The procurement team commenced the tender process, using the Delta E-tendering portal, on 30 May 2017 by placing electronic advertisements in Contracts Finder (UK Government public sector website) and in the Official Journal of the European Union (OJEU), seeking expressions of interest and requesting pre-qualification questionnaires (PQQ) from potential suppliers.

- 2.2 On the closing date the GPhC had received completed PQQ's from five suppliers. Following evaluation by the procurement all five potential suppliers were invited to tender (ITT).
- 2.3 The ITT process closed on 21 July 2017 and procurement received bids from four potential suppliers. The ITTs were evaluated and scored against criteria by David Price, Procurement Manager, and Ruth McGregor, Head of Finance and Procurement. The two highest scoring suppliers were; Crowe, Clark & Whitehill, and Haysmacintyre. It was agreed with Megan Forbes, Deputy Chief Executive & Director of Operations, that both would be invited to a supplier presentation day on 2 August 2017. Attendees at the presentations included Digby Emson, chair of ARC; Helen Dearden, independent ARC member; Mark Hammond, ARC member and David Price.
- 2.4 Adjusting for variation in the two proposals for delivering the audit plan, both companies were within the acceptable budget for the provision of the external audit service.
- 2.5 Following the supplier presentations the panel discussed the benefits and weaknesses of the approaches outlined by the two companies. The panel felt that Crowe, Clark & Whitehill be would be well placed to meet the needs of the GPhC and recommend that they are appointed for a period of three years.
- 2.6 In order to appoint the new service provider Council needs to request the resignation of the previous provider, Grant Thornton. This will allow for the handover between providers.

3. Equality and diversity implications

- 3.1 There are no equality and diversity implications that arise directly out of this paper.

4. Communications implications

- 4.1 The appointment of external auditors will be communicated to staff and stakeholders as appropriate. Induction arrangements will be put in place to ensure that lines of communication are established before the audit process begins.

5. Resource implications

- 5.1 The budget for external audit is included in routine, annual expenditure.

6. Risk implications

- 6.1 Failure to appoint external auditors will mean that the GPhC will not be compliant with its accounting requirements.

Recommendation

The Council is asked to:

- i. formally request the resignation of the previous external auditors, Grant Thornton
- ii. appoint, following the recommendation of the Audit and Risk Committee tender panel, Crowe, Clark & Whitehill as external auditors for a period of three years

Digby Emson, Chair Audit and Risk Committee

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12 September 2017