Public business

1. Attendance and introductory remarks
   Nigel Clarke

2. Declarations of interest
   Public items
   All

3. Minutes of last meeting
   Public session on 08 November 2018
   Nigel Clarke

4. Actions and matters arising
   Nigel Clarke

5. Workshop summary
   Nigel Clarke

6. Preparing for the UK’s exit from the EU
   For noting
   18.12.C.01
   Osama Ammar

7. Standards for independent prescribers
   For approval
   18.12.C.02
   Mark Voce

8. Update on safe and effective pharmacy team guidance
   For noting
   18.12.C.03
   Mark Voce

9. Developing our approach to regulating registered pharmacies
   For approval
   18.12.C.04
   Claire Bryce-Smith

10. Update on our work on the Gosport Independent Panel Report
    For noting
    18.12.C.05
    Laura McClintock

11. Review of Council workshops – six-month update
    For noting
    18.12.C.06
    Laura McClintock

12. Any other public business
    Nigel Clarke
Confidential business

13. Declarations of interest
   Confidential items

14. Minutes of the last meeting
   Confidential session on 8 November 2018

15. Confidential actions and matters arising

16. Minutes of the Efficiency and Effectiveness Assurance and Advisory Group – 11 November 2018

17. Any other confidential business

Date of next meeting

Thursday, 07 February 2019
Minutes of the Council meeting held on Thursday 8 November 2018 at 25 Canada Square, London at 13:30

TO BE CONFIRMED 6 DECEMBER 2018

Minutes of the public session

Present

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

Apologies

Berwyn Owen

In attendance

Duncan Rudkin (Chief Executive and Registrar)
Claire Bryce-Smith (Director of Insight, Intelligence and Inspection)
Matthew Hayday (Interim Director of Fitness to Practise)
Francesca Okosi (Director of People)
Mark Voce (Director of Education and Standards)
Laura McClintock (Chief of Staff)
Professor Andrew Husband (Chair of the Board of Assessors)
Janet Collins (Governance Manager)
Terry Orford (Head of Customer Service)
Damian Day (Head of Education)
67. Attendance and introductory remarks
67.1 The Chair welcomed all present to the meeting.

68. Declarations of interest
68.1 Council agreed that members would make any declarations of interest before each item.

69. Minutes of the last meeting
69.1 The minutes of the public session held on the 11 October 2018 were confirmed as a fair and accurate record.

70. Actions and matters arising
70.1 Claire Bryce-Smith (CBS) updated the Council on action reference 61.1 from the October meeting. There were three elements: wider work on analysis and reporting, which was live as part of the 2019-20 business planning and would be reported to Council in February 2019; the quarterly progress report which would include qualitative and quantitative evaluation of inspection reports and would be presented at a workshop in February 2019; and refinements to the inspection model which would be put to Council for approval in December.

70.2 All other actions were in hand.

71. Workshop summary – 11 October 2018
71.1 Council noted the discussions from the workshop.

72. Performance monitoring and annual plan progress report
72.1 Duncan Rudkin presented 18.11.C.01. The paper reported on operational and financial performance and progress against the annual plan from July to September 2018.

Customer Services
72.2 In relation to the registration figures, it was noted that it would be useful to have previous quarters’ figures provided alongside for comparison.

72.3 One member asked for confirmation that the median application processing time from receipt to approval was actually zero days for pharmacy technicians. This was confirmed.

72.4 Members raised a number of questions about the percentage of abandoned calls for Q2. Terry Orford (TO) explained that 2018 had been an exception in terms of call volumes, with the introduction of both MyGPhC and Revalidation. Call volumes in relation to both had been high and the degree of support needed and given meant that calls could be lengthy. There was feedback that registrants had appreciated the support they received. MV noted that the underlying trends in relation to the quality of advice given and the stability of the centre were positive.

72.5 There was uncertainty in the pharmacy community about the introduction of the peer discussion and reflective account elements of revalidation and that this could lead to another rise in calls. A question was raised as to whether this was being planned for. TO responded that it was, and that training would be provided for staff and reference materials for registrants. Members agreed that data on call length and call types would be useful.

72.6 While it was always difficult to know how much detail to provide, it was agreed that the text in relation to the Contact Centre’s performance against its KPIs was too sparse. Analysis of the reasons and assurance of what was in place to ensure improvement were needed. The Efficiency and Effectiveness Assurance and Advisory Group (EEAAG) would look in more detail at the issues.

**ACTION: MV**

Fitness to Practise

72.7 There was a correction to the FtP data. In 2.8 (Interim Orders - IO), the median period taken from receipt of information identifying the possible need for an IO to the application being heard had decreased to 1.9 weeks.

72.8 Council welcomed the information provided about cases over 52 weeks old which were with other authorities. While it had always been the case that such cases were held by the GPhC until other proceedings were complete, advice was being sought as to whether that should continue.

*Inspections*

72.9 Members discussed table 3.4 – top five standards ranked as not met. There was continued concern that standard 2.1 – the requirement for safe staffing levels – was still in the top five although it had dropped to fifth place. There was some discussion about what happens in pharmacies that fail this standard – All pharmacies rated ‘poor’ were
required to create and implement an action plan to address the deficiencies identified by the inspector. CB-S explained that while the GPhC did not recommend specific actions that a pharmacy should take, it did ask what the actions would be, assess the proposal and follow up.

72.10 One member noted that, with the arrival of standard 1.6 in the top five, there were now two standards in that list which related to controlled drugs and asked whether there might be a connection.

72.11 Julian Graville (JG) responded that there had been 343 instances in the past five years of pharmacies failing to meet standards 1.6 and 4.3. The team was looking to understand any correlation and what it might mean for patient safety.

Human Resources

72.12 There was some discussion around absence management, performance management, health and wellbeing and induction. FO noted that the EEAAG and the Council would see the Organisational Development Strategy which was being produced.

72.13 In Table 6.3, it was agreed that grievance and disciplinary cases should not be reported together as they were very different in nature.

**ACTION: FO**

*Annual Plan progress report, Q2 July-September 2018*

72.14 A member questioned the several references to the impact of the General Data Protection Regulations (GDPR) and inquired what the impacts were. CB-S responded that the GPhC was receiving more numerous and more complex subject access requests involving numerous documents.

72.15 In response to a comment about resource levels in Fitness to Practise, MH noted that it had been necessary to re-focus some staff from development work to case through-put. DR noted that the team was considering whether certain types of investigation were currently over-resourced and whether the GPhC needed to be smarter about what it considered and more confident about saying that certain issues were not for fitness to practise (always with patient safety in mind). Council would be engaged in that work at the December workshop.

72.16 One member noted that it was important to keep an eye on the number of voluntary removals from the register in the context of the budget and possible loss of revenue. DR agreed and said this was being closely monitored. Updated registration figures were available and would be circulated to members by email.

72.17 **Council noted the report.**
73. Report on the feedback from the consultation on developing our approach to regulating registered pharmacies

73.1 Claire Bryce-Smith (CB-S) introduced 18.10.C.02, which provided the Council a report on the feedback from the consultation. The Chair stressed that the purpose of the paper was simply to provide Council with the feedback and not to make a decision at this stage.

73.2 The paper was presented by Mariya Stamenova (Policy Manager) and Ambrose Paschalides (Inspection Operations Manager). MS noted that feedback on the proposed creation of a knowledge hub for inspection reports and on the new types of inspection had been positive. A majority of respondents had supported the move to unannounced inspections, taking the view that it would be good for inspectors to see pharmacies in the same way that patients experience them. The proposed changes to outcomes had been more controversial, with some respondents feeling that it would be difficult to distinguish between minor faults and major failings.

73.3 There was support for the publication of inspection reports but less for the publication of action plans and the display of ratings. Some respondents suggested a scale of outcomes similar to that used by the Care Quality Commission. The most controversial proposal had been the proposed requirement for a pharmacy to meet every standard in order to pass the inspection.

73.4 Members welcomed the content of the report and the work that had gone into producing it. A member who had attended one of the consultation workshops noted that there had been a difference between the patients and registrants in attendance, with patients wanting to know as much as possible and registrants feeling concerned that a minor failing which could easily be corrected could lead to a pharmacy being branded as a failure overall.

73.5 The proposals would be presented to Council for decision in December.

**ACTION: CB-S**

73.6 Council noted the report.

74. Strategic plan 2017-20 – year three

74.1 DR presented 18.10.C.03, which proposed that the current Strategic plan 2017-20 should be updated with some minor revisions to the Foreword and sought feedback on the proposed revisions.

74.2 Members provided some helpful feedback.
74.3 Council approved the update to the Strategic plan 2017-20, with some minor revisions, and agreed that the Foreword should be finalised by DR and the Chair.

**ACTION:** DR and NC

75. Initial Education and training for pharmacists – standards and consultation document

75.1 Mark Voce (MV) and Damian Day (DD) presented 18.10.C.04 which presented Council with a consultation document on revised initial education and training (IET) standards for registered pharmacists.

75.2 The key proposed changes included:

i) Learning outcomes focussed on four themes, namely person-centred care; professionalism; professional knowledge and skills; and collaboration.

ii) Integrating the five years of IET, setting the learning outcomes to be achieved over five years.

iii) Learning in practice – there will not be a separate set of pre-registration performance standards

iv) Selection and admission will assess the values of prospective students as well as their academic ability through face to face interviews; and

v) Equality and diversity – providers will be required to conduct an annual review of student admission and performance by the protected characteristics set out in the Equality Act 2010.

75.3 Members welcomed the document and the proposed changes to IET, asked questions and made a number of helpful suggestions. There was some discussion about whether there was a correlation between acceptance of lower A-level grades and a lower pass rate at degree level.

75.4 A note of the changes to be included as a result of the discussion would be circulated to members.

75.5 Subject to those amendments, **Council approved the consultation document.**

76. Revalidation – 2019-20 submissions and Standards for pharmacy professionals

76.6 Osama Amman presented 18.10.C.05, which set out the three standards for pharmacy professionals on which registrants would be asked to base their reflective accounts for the 2019-20 cycle of revalidation.

76.7 The proposed standards were three (effective communication), eight (speaking up when things go wrong) and nine (demonstrating leadership). Number three had been used in
the pilot study and would provide a useful baseline. While three and nine were readily agreed, there was some discussion about number eight. Some members stated a preference for number six (behaving professionally) as it might be easier for all registrants to relate to for the first round of reflective accounts.

75.8 It was agreed that standard eight might not be suitable for the first round of reflective accounts and should be used at a later date.

75.9 **Council agreed that the standards for pharmacy professionals to be used for the 2019-20 reflective accounts would be standards three, six and nine.**

### 76 Policy and procedure review

76.1 Laura McClintock presented **18.10.C.06** which sought the Council’s approval for a number of policies and procedures within its remit which had been recently reviewed, namely.

- i) The updated terms of reference for the Efficiency and Effectiveness Assurance and Advisory Group (EEAAG);
- ii) The updated policy for the appointment of members of the Audit and Risk (ARC) and Remuneration Committees;
- iii) The updated Raising concerns policy;
- iv) The updated Anti-bribery policy; and
- v) The adoption of the Non-staff expenses policy by Council members.

76.2 **Council approved the updated terms of reference for the EEAAG, the three updated policies and the adoption of the Non-staff expenses policy by Council members.**

### 77 Registration assessment and Board of Assessors’ report – June and September 2018

77.1 DD introduced the Registration assessment data and Professor Andy Husband, Chair of the Board of Assessors was welcomed to the meeting to present the report of the Board of Assessors (both set out in **18.10.C.07**).

77.2 Professor Husband stated that the Board had continued to refine its processes, particularly in relation to standard setting. There had been some changes to the Board due to the departure of one member and the death of another.

77.3 Members asked about the pass rates for candidates aged 36 and over, which was lower than for other age groups, and whether there was anything that could be done. However, without multiple regression analyses, it was not possible to determine whether age was the independent variable responsible. It was noted that support for any group of candidates was a role for the professional bodies, rather than the regulator, provided
that the process was fair. The Board was confident that the questions did not select out or disadvantage any particular group and was therefore fit for purpose.

77.4 There was further discussion about the possible link between A-level grade offers for places and subsequent pass/fail rates, with particular reference to unconditional offers. While it was noted that some ‘unconditional’ offers were made to students who had already taken their A-levels and obtained good grades, there was evidence that when such offers were made to students yet to sit their A-levels, they acted as a de-motivator which could have an impact later in the students’ careers.

77.5 The Council noted the report and thanked Professor Husband. The council recorded its thanks for the services of Karen Pitchford and its condolences to her family.

78 Remuneration Committee minutes (unconfirmed), September 2018

78.1 LM introduced 18.10.C.08 which set out the unconfirmed minutes of the meeting of the Remuneration Committee held on 27 September 2018.

78.2 In response to a question, FO updated the members on the progress of the reward and recognition work, which was on track and would be presented to the Remuneration Committee in February 2019 with a view to being signed off in April 2019.

78.3 The Council noted the minutes of the Remuneration Committee.

79 Council member remuneration

79.1 LM introduced 18.10.C.09 which set out proposed levels of remuneration for the Chair and Council members from April 2019. No changes were proposed.

79.2 All members declared an interest.

79.3 The Council agreed that the remuneration for Council members and the Chair of Council and the discretionary payments for the Chairs of the Audit and Risk and Remuneration Committees and the EEAAG should remain unchanged.

79.4 The Council also agreed that there should be a comprehensive ‘deep dive’ into member remuneration every two years.

80 Audit and Risk Committee minutes (unconfirmed), October 2018

80.1 Digby Emson introduced 18.10.C.10 which set out the unconfirmed minutes of the meeting of the Audit and Risk Committee held on 23 October 2018.

80.2 It was noted that the figure suggested by the committee as an acceptable minimum level for the reserves was two to three months (2-3) and not 2.3 months as shown. This would be corrected.

80.3 The Council noted the minutes of the ARC.
81 Any other business

81.1 There being no further public business to discuss the meeting closed at 15:00.

Date of the next meeting:
Thursday 6 December 2018
## Council actions log

<table>
<thead>
<tr>
<th>Meeting date</th>
<th>Ref.</th>
<th>Action</th>
<th>Owner</th>
<th>Due date</th>
<th>Status</th>
<th>Comments/update</th>
</tr>
</thead>
<tbody>
<tr>
<td>13 September 2018</td>
<td>52.3.</td>
<td>Revised draft standards combining a time and competency approach to independent prescribing programmes would be brought to Council, as well as further analysis of the feedback to the consultation by sector.</td>
<td>MV</td>
<td>Dec 18</td>
<td>Open</td>
<td>On the agenda for this meeting</td>
</tr>
<tr>
<td>11 October 2018</td>
<td>61.1.</td>
<td>CB-S to report back to Council on granularity of reporting on standards met and not-met (eg. standard 4.3) in the wider context of our work on analysis and reporting across a range of fronts.</td>
<td>CB-S</td>
<td>Feb 19</td>
<td>Open</td>
<td>Three elements:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Analysis and reporting – live as part of business planning and will come to Council in February 2019;</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Quarterly progress report – including analysis of inspection report - Council workshop in February 2019; and</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>• Refinements to the inspection model – on the agenda for this meeting</td>
</tr>
<tr>
<td>8 November 2018</td>
<td>72.6</td>
<td>Data and proposals in relation to the Contact Centre to be considered by EEAAG</td>
<td>MV</td>
<td>Feb 19</td>
<td>Open</td>
<td>On the EEAAG agenda for February</td>
</tr>
<tr>
<td>8 November 2018</td>
<td>73.5</td>
<td>Final proposals on regulating registered pharmacies to Council in December</td>
<td>CB-S</td>
<td>Dec 18</td>
<td>Open</td>
<td>On the agenda for this meeting</td>
</tr>
<tr>
<td>Meeting date</td>
<td>Ref.</td>
<td>Action</td>
<td>Owner</td>
<td>Due date</td>
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<td>Comments/update</td>
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<td>----------------------------------------------------</td>
</tr>
<tr>
<td>8 November 2018</td>
<td>74.3</td>
<td>DR and NC to finalise the updated Foreword to the Strategic Plan 2017-20</td>
<td>DR</td>
<td>Dec 18</td>
<td>Closed</td>
<td>The text was agreed and the Plan has been laid.</td>
</tr>
<tr>
<td>8 November 2018</td>
<td>18.12.C00d Workshop summary</td>
<td>Executive to prepare a protocol for the handling of patient safety issues, for discussion with Council</td>
<td>DR</td>
<td>Jan 19</td>
<td>Open</td>
<td>Ongoing</td>
</tr>
</tbody>
</table>
Meeting paper

Council on Thursday, 06 December 2018

Public business

Council Workshop Summary

Purpose
To provide an outline note of the discussions at the Council workshop in October.

Recommendations
The Council is asked to note the discussions from the workshop.

1. Introduction

1.1. The Council holds a workshop session alongside its regular Council meetings each month (there are no meetings in January and August). The workshops give Council members the opportunity to:

- interact with and gain insights from staff responsible for delivering regulatory functions and projects;
- receive information on projects during the development stages;
- provide guidance on the direction of travel for work streams via feedback from group work or plenary discussion; and
- receive training and other updates.

1.2. Following each workshop there is a summary of the discussions that took place, presented at the subsequent meeting. This makes the development process of our work streams more visible to the GPhC’s stakeholders. Some confidential items may not be reported on in full.

1.3. In the workshop sessions the Council does not make decisions. The sessions are informal discussions to aid the development of the Council’s views. This workshop was shorter than usual as the agenda for the main meeting was substantial.

2. Summary of the October workshop

2.1. Clinical Fellowship schemes

Neha Ramaiya (NR) and Nicky Nardone (NN) gave an overview of the fellowship schemes, their backgrounds and the projects that they will be working on during their 12 months at
the GPhC. The scheme allows members of the profession to work with senior pharmacy leaders in national NHS and healthcare-related organisations, developing skills in leadership, strategy, project management and health policy.

2.2 NR would be working on establishing a baseline and assessment of clinical practice for all pharmacy settings, with a view to increasing the GPhC’s understanding of the range of clinical practice and raising the clinical consciousness of the organisation.

2.3 NR’s project would include developing an inspection methodology to incorporate assessment of the quality of clinical services (linking to the ten-year vision) and providing assurance that pharmacy staff have the required knowledge and skillset to provide clinical services (supporting the development of professionals to meet the healthcare needs of patients and the public). There would also be work on developing example case studies of notable practice for the Knowledge Hub.

2.4 NN would be working on projects for the Scottish Government and the GPhC. This was the first year that Scotland had included pharmacy in their clinical fellowship schemes. NN’s work for the GPhC would include professionalism and a review of FtP cases involving pharmacy technicians. The professionalism work would seek to increase the GPhC’s understanding of the differing scopes of practice undertaken by pharmacy technicians, their understanding of professional standards and their practical application, including drivers and barriers.

2.5 **Update on recent patient safety issues in the external context**

Council members were given an update on the actions taken by the GPhC in the interests of patient safety in relation to Valproate, Avastin and Epipen. The GPhC’s actions had been informed by key parts of the 10-year vision, including using communication as a regulatory tool, delivering tailored regulatory responses and always focussing on patient safety.

2.6 The actions included making clear statements that registrants acting in accordance with the law would not face FtP sanctions, communicating with all registered pharmacy professionals, asking specific questions on inspections, writing articles, working collaboratively with the DHSC and emphasising the importance of effective communication with patients and carers and speaking to prescribers in more complex cases.

2.7 The executive would prepare a protocol for the handling of such issues, which would be discussed with the Council.
**Recommendations**
Council is asked to note the discussions from the workshop

**Janet Collins, Governance Manager**
General Pharmaceutical Council

janet.collins@pharmacyregulation.org

Tel 020 3713 8139

26 November 2018
Meeting paper
Council on Thursday, 06 December 2018

Public business
Exiting the European Union – preparations for exit

Purpose
To outline for the Council the impact on pharmacy regulation of the UK’s exit from the European Union (EU) and the work taking place to prepare for change.

Recommendations
The Council is asked to note this paper which serves to draw out the main issues for future discussion at Council.

1. Introduction
1.1. The UK is due to leave the EU on 29 March 2019. A draft deal has been agreed between the UK and EU, upon which Parliament will vote on 11 December 2018. Article 126 of the draft deal states there will be a “transition or implementation period” which will end on 31 December 2020. There is an option to gain agreement before 1 July 2020 for an extension of the transition or implementation period.

1.2. The content of this paper is focused on the impact of a transition or implementation period. Conversations with officials are taking place to prepare for other forms of exit.

2. Broad areas of impact
2.1. We anticipate that there will be impacts across broad areas of pharmacy and pharmacy regulation. These areas do not all relate directly to our own regulatory functions but may have an impact on users of pharmacy services, pharmacy professionals and pharmacies and have an indirect effect on our work. These broad areas are:

- routes to registration
- pharmacist education and training requirements
- the pharmacy workforce
• European Professional Card and European Alert Mechanism
• medicines and device regulation and pharmacy practice
• medicines supply
• operations within GPhC

Routes to registration

2.2. The European Directive for Mutual Recognition of Qualifications sets out that people with qualifications and / or rights to practise as a pharmacist or pharmacy technician from an EU member state have the right to streamlined application routes to our Register owing to the assurance we can take from regulatory alignment from EU membership. The effect is that there are a number of additional routes to registration for EEA qualified pharmacists or pharmacy technicians.

2.3. When the UK leaves the EU we will no longer be a member state and we will therefore no longer be automatically included in these arrangements.

2.4. Under a transition or implementation period we would operate our existing routes to registration for EEA qualified pharmacy professionals until a future arrangement is agreed and the Pharmacy Order amended accordingly.

Pharmacist education and training requirements

2.5. In the case of pharmacist initial education and training, the European Directive for Mutual Recognition of Qualifications also sets out common expectations including for content and duration of training.

2.6. Under a transition or implementation period we would continue to be bound by these requirements when setting standards for initial education and training for pharmacists until agreement on the future relationship is reached.
The pharmacy workforce

2.7. Organisations, such as HEE, NES and HEIW, hold the responsibility for ensuring there are sufficient numbers of appropriately qualified pharmacists and pharmacy technicians in the workforce to support health and social care delivery in Great Britain.

2.8. Our role is to protect the public by ensuring access to the register is only given to those who have the required knowledge, skills and behaviours for safe and effective practice in line with legislative provision.

2.9. We hold data on numbers of registrants and applicants that bodies responsible for workforce planning request periodically to fulfil their responsibilities and which provide a picture of how many European Economic Area (EEA) pharmacy professionals are currently registered.

2.10. Below is data presented in tables and graphs that show the number of EEA registrants and applicants from 2013-18. There are two notes on the data as it is presented:

- The total number of registrants used to calculate the percentage of the register is the number of pharmacists or pharmacy technicians on the register on 30 September 2018. These were 57,098 pharmacists and 23,493 pharmacy technicians.
- Data for 2018 is incomplete as it was extracted in November and figures may increase over the course of December.

Table one – EEA pharmacist registrants and initial registrations 2013-18

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of pharmacists</td>
<td>2,832</td>
<td>2,976</td>
<td>3,139</td>
<td>3,305</td>
<td>3,601</td>
<td>3,416</td>
</tr>
<tr>
<td>Percentage of register</td>
<td>5.0</td>
<td>5.2</td>
<td>5.5</td>
<td>5.8</td>
<td>6.3</td>
<td>6.0</td>
</tr>
<tr>
<td>Number of initial registrations as a pharmacist</td>
<td>391</td>
<td>391</td>
<td>467</td>
<td>526</td>
<td>69</td>
<td>91</td>
</tr>
</tbody>
</table>
Graph one – EEA pharmacist registrants and initial registration 2013-2018

Table two - EEA pharmacy technician registrants and initial registrations 2013-18

<table>
<thead>
<tr>
<th></th>
<th>2013</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of pharmacy technicians</strong></td>
<td>175</td>
<td>187</td>
<td>189</td>
<td>198</td>
<td>210</td>
<td>218</td>
</tr>
<tr>
<td><strong>Percentage of register</strong></td>
<td>0.7</td>
<td>0.8</td>
<td>0.8</td>
<td>0.8</td>
<td>0.9</td>
<td>0.9</td>
</tr>
<tr>
<td><strong>Number of initial registrations as pharmacy technician</strong></td>
<td>18</td>
<td>15</td>
<td>20</td>
<td>16</td>
<td>16</td>
<td>4</td>
</tr>
</tbody>
</table>
2.11. These data only show application route and current registration with GPhC and cannot be used to make assertions about current registrant location (some may not be practicing routinely in the UK for example) or settlement status (some may for example be UK citizens who trained in the EEA).

2.12. For pharmacists there has been a reduction in the number of initial registrations in 2017 and 2018 compared to previous years. This could be caused by a number of factors. One factor may be that we introduced more stringent requirements for evidence of English language attainment for EEA applicants in November 2016 which we promoted in advance of their introduction to applicants. We believe this is the reason that there is an above average increase in the number of EEA pharmacists in 2016. In 2018, we have seen the number of EEA pharmacists on the register reduce for the first time.

2.13. For pharmacy technicians there has also been a reduction in the number of initial registrations in 2018, but the overall trend of increase in registrant numbers has continued.

2.14. Our data does not provide any information on the support staff workforce for pharmacy which is an additional consideration for employers in the pharmacy sector.

2.15. No matter the form of exit, the Government has indicated that EEA professionals who are already established and have a decision of recognition from a UK competent authority will remain unaffected.
2.16. The Government has also taken steps to secure settled status for EU citizens. In December 2018, staff in the health and social care sectors (including pharmacists, pharmacy technicians on the GPhC register and GPhC staff) across the UK will be eligible to apply to a pilot scheme and the full scheme will be open by 30 March 2019.

European Professional Card and European Alert Mechanism

2.17. The International Market Information (IMI) system is a European database used to administer cross-border information exchange across public authorities in Europe. The IMI is used to administer two processes.

2.18. The European Alert Mechanism provides a route for competent authorities to raise alerts on registrants and share information across member state competent authorities. The alert mechanism is a secondary system as we already produce monthly alerts for UK organisations and overseas competent authorities. Under a transition or implementation period we will be able to continue to use IMI to issue and receive alerts.

2.19. The European Professional Card is an electronic certificate issued through the IMI which in effect is a route to registration for EEA qualified pharmacists. Under a transition or implementation period we will be able to continue to use IMI to and therefore will continue to receive applications to the register through the IMI.

Medicines and device regulation and pharmacy practice

2.20. The responsibility for medicines and device regulation rests with the Medicines and Healthcare products Regulatory Authority (MHRA). Although regulatory responsibility is held elsewhere, this information is provided because of its impact on users of pharmacy services, the pharmacy sector and the work of our co-regulator and indirect impact on pharmacy regulation.

2.21. The Falsified Medicines Directive has a deadline for implementation on 9 February 2019 and requires an anti-tampering device and unique pack identifier to be placed on the packaging of most human medicines. We expect this requirement to continue no matter the form of exit.

2.22. Already fully implemented is the EU logo for online sale of medicines which is issued by MHRA. Under a transition or implementation period the MHRA will continue issuing the logo.

2.23. Clinical trials legislation which is derived from EU legislation will in part remain in force no matter the form of exit. A transition or implementation period will ensure that Clinical Trials Regulation (CTR) 536/2014, a more recent regulation, will be in force until a future relationship is agreed by the UK and EU.
**Medicines supply**

2.24. A higher profile matter and one that may more directly affect public safety and health is medicines supply. The responsibility for medicines supply rests collectively across the Government and the supply chain.

2.25. Working collaboratively, parties are making preparations to assure sufficient supply.

2.26. A transition or implementation period will introduce no additional regulatory or customs burden on the medicines supply chain.

**Operations within GPhC**

2.27. There are a number of operational functions affected by exiting the European Union. A review of the technical notices to support organisations to adapt to exiting the European Union was undertaken. A transition or implementation period would mean we would be able to continue to operate in the same way until a future relationship is agreed between the UK and EU. The areas subject to review were:

- Copyright, trademarks and designs
- Data protection
- Vehicle insurance, driving in the EU and flights to and from the UK for any staff who may be affected
- Accessing public sector contracts
- Accounting and audit
- Banking, insurance and other financial services
- VAT for businesses
- Workplace rights
- Handling civil legal cases that involve EU countries

**3. Equality and diversity implications**

3.1. A full analysis will be undertaken once all parties have agreed the form of exiting the EU. Under a transition or implementation period the impact of change is minimal in the short term but will require monitoring over the course of agreeing the future relationship between the UK and EU.
4. **Communications**

4.1. Until there is certainty over the form of exit, communications should be limited to only those things which are certain. We have made it clear to EEA registrants that their registration will remain unaffected and assisted with communications over the pilot settlement scheme.

4.2. It is possible that we may only be able to communicate at a late stage in the exit process or be required to quickly communicate lots of complex information to the sector if progress is made at the stages of agreement.

5. **Resource implications**

5.1. Owing to the uncertainty, a contingency budget has been set aside for 2019/20 rather than a fully costed budget.

5.2. Staff time in this financial year has been accounted for in planning, however it is possible that as the next stages of agreeing the deal for exit proceeds that more staff time will be required to support rapid activities with short deadlines.

6. **Risk implications**

6.1. Routine risk management and monitoring has been continuous. A transition or implementation period will maintain current arrangements and therefore risks will not change in their character. But ongoing monitoring will be required during negotiations on the future relationship.

7. **Monitoring and review**

7.1. Monitoring is continuous and daily. Council will be given the opportunity to revisit any decisions related to the UK’s decision to exit the EU if the nature of exit changes.

**Recommendations**

The Council is asked to note this paper which serves to draw out the main issues for future discussion at Council.

**Mark Voce, Director of Education and Standards**

General Pharmaceutical Council

28 November 2018
Meeting paper

Council on Thursday, 06 December 2018

Public business

Implementing revised education and training standards for pharmacist independent prescribers

Purpose
To present Council with a revised set of education and training standards for pharmacist independent prescribers, incorporating feedback from a formal consultation, for final approval.

Recommendation
Council is asked to agree revised education and training standards for pharmacist independent prescribers.

1. Introduction

This paper sets out how we consulted on revised standards for pharmacist independent prescribers and our proposals for a final set of revised standards in light of the consultation responses and earlier Council feedback.

Our development work began in November 2016 when we published a discussion paper on the supervision of pharmacist independent prescribers in training. In late 2017 this was followed by pre-consultation meetings with all schools of pharmacy and other providers of pharmacist independent prescribing courses. We launched a formal consultation on revised standards in March 2018 and presented a report on the consultation to Council in September 2018. We have now completed our consideration of the points raised in response to the consultation, including Council’s feedback, and prepared a final draft of the standards.
2. Proposed changes and how we have addressed the responses to the consultation

In our 2018 consultation we proposed three main changes to the current standards:

- Introducing revised learning outcomes;
- a change to the entry requirements for independent prescriber courses
- the introduction of designated prescribing practitioners; and

Introducing revised learning outcomes: Respondents agreed with us that the revised outcomes we were proposing described accurately the knowledge, skills and attitudes required of a contemporary pharmacist independent prescriber. We have made some drafting changes in light of the consultation responses and sense-checked the revisions with expert advisory group. We have also strengthened the standards in respect of the use of technology in prescribing and the promotion of equality and diversity. This reflects Council feedback from the separate, but related, discussion on revised initial education and training standards for pharmacists.

A change to the entry requirements for IP courses: Currently, pharmacists are required to have worked in a relevant, patient-facing area for two years before applying to train as an IP. Having received feedback from some course providers that time served (a quantitative measure) was not an effective substitute for evaluating the quality and suitability of an applicant’s experience, we proposed that the time requirement should be removed, with greater emphasis placed on the nature of an applicant’s experience. Respondents’ views in the consultation were mixed and after a discussion in September, Council agreed (1) that the case for removing the time requirement had not been made with sufficient force and (2) that moving forward course providers should evaluate both the quality and quantity of an applicant’s experience. Consequently, the revised standards propose that the two-year requirement remains in place.

The introduction of designated prescribing practitioners (DPPs): Currently the practice supervision of pharmacist independent prescribers in training is undertaken by doctors, designated medical practitioners (DMPs). In November 2016 we issued a discussion paper suggesting that the supervision pool should be expanded to include suitably experienced non-medical independent prescribers, designated prescribing practitioners (DPPs). The principle was agreed by Council after considering the responses to our discussion paper.

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1 See Learning Outcomes Domain 1, Learning Outcome 2 & Domain 3, Learning Outcome 7 and Standards Domain 2, Standard 2 and Domain 2, Criterion 2.1.
2 See Entry Requirements 1.3.
Following on from the in-principle decision, in our 2018 consultation we asked for views on the introduction of a new standard, 9, fleshing out the requirements for DPPs. Overall, respondents agreed with the approach taken in the standard but most organisations did not.

The main issues accounting for the high number of ‘disagree’ responses to the question about Standard 9 mainly reflected concerns from the education and training sector. First, the standards were seen by course providers as increasing their obligations in respect of the quality management and support for DPPs, including mentoring. Second, both education organisations and NHS stakeholders wanted more detailed guidance around how DPPs would demonstrate competence.

Other organisations across sectors echoed the second point above and emphasised the importance of retaining medical input in to the supervision mix.

To mitigate the issues raised we have done/will do the following:

1. Removed the requirement for formal mentoring of DPPs (while retaining the general requirement for course providers to support and quality assure professionals working for them). On reflection we have decided that a formal mentoring requirement may not be necessary as DPPs are required to be suitably experienced before taking on the role.

2. Publish a detailed evidence framework to accompany these standards and make clear that the introduction of DPPs does not diminish the importance of input from other prescribing professionals and that supervision models may well be multi-professional.

3. In 2016 the Royal Pharmaceutical Society (RPS) produced A competency framework for all prescribers, in consultation with a wide range of professional bodies and regulators. We have approached the RPS about producing a supplement to the Framework, providing guidance for DPPs. We have discussed this with several other healthcare regulators and they agree with this approach. The RPS has secured funding for the supplement and will begin work on it in 2019: their estimate is that it will take 12 months to complete. Before the guidance is issued we propose that course providers should be allowed to introduce DPPs if they are able to do so. They will make the case by submitting a supplement to their accreditation submission which will be evaluated by our accreditors.

3. **Next steps**

*Evidence framework:* We are finalising the evidence framework to accompany these standards and will test it with course providers in early 2019. Once tested and finalised it will be issued to all course providers.
Accreditation of new courses: We will begin to accredit courses based on the new standards in 2019. This will be done on a phased basis, as it always is, over the next few years. Should a course provider wish to revise their course before their current period of accreditation expires we will do our best to accommodate them.

Translation into Welsh: Once agreed, the new standards will be translated into Welsh (and issued at the same time as the English version).

4. Equality and diversity implications

Equality and diversity issues are discussed in the equality impact assessment accompanying this paper (Appendix 2).

As discussed in 2. above, and in response to Council feedback on other standards, we have added a requirement to promote equality and diversity.

5. Communications

Depending on the outcome of Council’s discussion, the standards will be issued directly to all course providers and other interested parties.

6. Resource implications

Routine and some earlier than planned course reaccreditations have been budgeted for.

7. Risk implications

If the new standards are not introduced, courses will continue to be accredited against standards which are now nearly 13 years’ old and now not fully reflective of contemporary prescribing practice.

8. Monitoring and review

We will monitor the impact of introducing the new standards through the accreditation process and will report back to Council in due course.

Recommendation

Council is asked to agree revised education and training standards for pharmacist independent prescribers

Damian Day, Head of Education
General Pharmaceutical Council

damian.day@pharmacyregulation.org

November 23rd 2018
Appendix 1

Draft standards begin here

Standards for the education and training of pharmacist independent prescribers

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

What we do
Our main work includes:

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

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

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

Before training to prescribe, pharmacists must have experience of working in a particular clinical area. The area is the one in which the pharmacist will learn how to prescribe.

These standards describe (1) the knowledge and skills pharmacist independent prescribers will achieve during their education and training and (2) our requirements for course providers.

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

The prescribing role

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

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

On successful completion of an independent prescribing course trainees must have demonstrated this.
The structure of the standards

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

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

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

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

1. Domain 1 – Selection and entry requirements;
2. Domain 2 – Equality, diversity and inclusion;
3. Domain 3 – Management, resources and capacity;
4. Domain 4 – Monitoring, review and evaluation;
5. Domain 5 - Course design and delivery;
6. Domain 6 – Training in practice;
7. Domain 7 – Assessment;
8. Domain 8 – Support and the learning experience; and
Part 1: Education and training standards for pharmacist independent prescribers – learning outcomes

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

Level of study

The level of study for pharmacist independent prescriber courses is Master’s level\(^1\), as defined in national qualifications frameworks.

Minimum learning time requirements

Teaching, learning and assessment are matters for course providers, but there must be at least:

1. 26 days of structured learning activities, and
2. 90 hours of learning in practice.

Learning activities

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

Learning in practice

‘Learning in practice’ time is when pharmacist independent prescribers in training practise and develop their clinical, diagnostic and prescribing skills under the supervision of other healthcare professionals. This includes their designated prescribing practitioner (who is responsible for signing off a pharmacist independent prescriber in training as being a competent prescriber).

Domains of study

Learning outcomes are presented under four domains:

1. person-centred care;
2. professionalism;
3. professional knowledge and skills; and
4. collaboration.

The domains and learning outcomes are all equally important.

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\(^1\) The majority of current prescribing courses are at Master’s level already.
Learning outcomes

In these standards Miller’s Triangle is used to set the outcome level. Miller’s triangle is a knowledge and competence hierarchy describing four levels of outcome:

1. ‘knows’ (knowledge),
2. ‘knows how’ (application of knowledge),
3. ‘shows how’ (demonstrate competence in a limited way)
4. ‘does’ (demonstrates competence repeatedly and safely).

The outcomes in these standards have been set at the right level for pharmacist independent prescribers in training.

The learning outcomes are:

Domain 1: Person-centred care

<table>
<thead>
<tr>
<th>Pharmacist independent prescribers at the point of registration will be able to:</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Recognise the psychological and physical impact of prescribing decisions on people</td>
<td>Knows how</td>
</tr>
<tr>
<td>2. Recognise, value <strong>and promote</strong> diversity, and respect cultural differences, making sure that every person is treated fairly whatever their values and beliefs</td>
<td>Does</td>
</tr>
<tr>
<td>3. Demonstrate appropriate history-taking techniques through effective consultation skills</td>
<td>Does</td>
</tr>
<tr>
<td>4. Demonstrate an understanding of the role of the prescriber in working in partnership with people who may not be able to make fully informed decisions about their health needs</td>
<td>Shows how</td>
</tr>
<tr>
<td>5. Support individuals to make informed choices that respect people’s preferences</td>
<td>Does</td>
</tr>
</tbody>
</table>

Domain 2: Professionalism

<table>
<thead>
<tr>
<th>Pharmacist independent prescribers at the point of registration will be able to:</th>
<th>Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Demonstrate a critical understanding of their own role and the role of others in multi-professional teams</td>
<td>Does</td>
</tr>
<tr>
<td>2. Recognise their own role as a responsible and accountable prescriber who understands legal and ethical implications</td>
<td>Does</td>
</tr>
<tr>
<td>3. Apply relevant legislation and ethical frameworks related to prescribing, including remote prescribing and the handling and sharing of confidential information</td>
<td>Shows how</td>
</tr>
<tr>
<td>4. Recognise and manage factors that may influence prescribing decisions</td>
<td>Does</td>
</tr>
<tr>
<td>Domain 3: Professional knowledge and skills</td>
<td></td>
</tr>
<tr>
<td>---------------------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Pharmacist independent prescribers at the point of registration will be able to:</strong></td>
<td><strong>Level</strong></td>
</tr>
<tr>
<td>1. Apply evidence-based decision making in all aspects of prescribing</td>
<td>Does</td>
</tr>
<tr>
<td>2. Manage the risks and benefits associated with prescribing decisions</td>
<td>Does</td>
</tr>
<tr>
<td>3. Demonstrate the application of pharmacology in relation to their own prescribing practice</td>
<td>Does</td>
</tr>
<tr>
<td>4. Demonstrate clinical and diagnostic skills in clinical settings appropriate to their scope of practice</td>
<td>Does</td>
</tr>
<tr>
<td>5. Create and maintain appropriate records which ensure safe and effective care and align with relevant legislation</td>
<td>Does</td>
</tr>
<tr>
<td>6. Identify relevant investigations and interpret results and data in their prescribing practice</td>
<td>Does</td>
</tr>
<tr>
<td>7. Utilise current and emerging systems and technologies in safe prescribing</td>
<td>Does</td>
</tr>
<tr>
<td>8. Identify and respond to people’s need when prescribing remotely</td>
<td>Shows how</td>
</tr>
<tr>
<td>9. Apply the principles of effective monitoring and management to improve patient outcomes</td>
<td>Does</td>
</tr>
<tr>
<td>10. Recognise and manage prescribing and medication errors</td>
<td>Shows how</td>
</tr>
<tr>
<td>11. Recognise the public health issues in promoting health as part of their prescribing practice</td>
<td>Does</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Domain 4: Collaboration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmacist independent prescribers at the point of registration will be able to:</strong></td>
</tr>
<tr>
<td>1. Work collaboratively with others to optimise individuals’ care, understanding their roles in the prescribing process</td>
</tr>
<tr>
<td>2. Recognise their own role and responsibilities, and those of others, in safeguarding children and vulnerable adults</td>
</tr>
<tr>
<td>3. Recognise when and where to refer people appropriately</td>
</tr>
</tbody>
</table>
Part 2: Standards for pharmacist independent prescribing course providers

Part 2 is made up of the entry requirements for a pharmacist independent prescriber course followed by nine standards and their associated criteria.

Entry requirements

The entry requirements for a pharmacist independent prescriber course are that:

1.1 Applicants are registered as a pharmacist with the General Pharmaceutical Council (GPhC) or, in Northern Ireland, with the Pharmaceutical Society of Northern Ireland (PSNI).

1.2 Applicants are in good standing with the GPhC and/or PSNI and any other healthcare regulator with which they are registered.

1.3 Applicants must have at least two years’ appropriate patient-orientated experience in a relevant UK practice setting post registration.

1.4 Applicants have an identified area of clinical or therapeutic practice in which to develop independent prescribing practice. They must also have relevant clinical or therapeutic experience in that area, which is suitable to act as the foundation of their prescribing practice while training.

1.5 Applicants must have a designated prescribing practitioner who has agreed to supervise their learning in practice. The applicant’s designated prescribing practitioner must be a registered healthcare professional in Great Britain or Northern Ireland with legal independent prescribing rights, who is suitably experienced and qualified to carry out this supervisory role, and who has demonstrated CPD or revalidation relevant to this role. Although an applicant may be supervised by more than one person, only one prescriber must be the designated prescribing practitioner. The designated prescribing practitioner is the person who will certify that successful pharmacists are competent to practise as independent prescribers.
Domain 1 – Selection and entry requirements

**Standard 1:** Selection processes must be open, clear and unbiased, comply with relevant legislation and ensure that applicants meet course entry requirements.

**Criteria to meet this standard**

1.1 Selection criteria must be clear and must include meeting all the entry requirements in these standards.

1.2 Selectors must apply the selection criteria consistently, in an unbiased way and in a way that meets the requirements of relevant legislation.

1.3 Course providers must provide clear guidance on the type of experience a pharmacist should have before applying to the course. This guidance must be available to applicants in advance of them making an application.

1.4 Course providers when considering applications, must evaluate the suitability and relevance of the applicant’s clinical and therapeutic experience (which the pharmacist must demonstrate in their application) against the requirements of the course.

1.5 A course provider must fully evaluate each application and decide if the applicant has sufficient and relevant experience to commence a course to train as an independent prescriber. If the course provider decides that there is insufficient relevant pre-requisite experience, they must reject the application, clearly setting out reasons behind this decision.

1.6 Course providers must ensure that all the pre-requisites have been met before the commencement date of a course on which an applicant is enrolled.

Domain 2 – Equality, diversity and inclusion

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

**Criteria to meet this standard**

2.1 The principles of equality and diversity must be embedded in, and promoted through, course design and delivery.
2.2 Equality and diversity data must be used when designing and delivering courses and the learning experience.

2.3 Reasonable adjustments must be made to course delivery to help pharmacist independent prescribers in training with specific needs to meet the learning outcomes.

2.4 Teaching, learning and assessment can be modified to meet 2.3 but learning outcomes cannot.

Domain 3 – Management, resources and capacity

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

Criteria to meet this standard

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

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

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

3.3 Learning agreements must be in place with the pharmacist independent prescriber in training covering all learning, teaching and practice environments outlining roles and responsibilities and lines of accountability.

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

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

3.5 Everyone involved in managing and delivering the course must understand their role and must be supported to carry out their work effectively.
3.6 Each pharmacist independent prescriber in training must be supported as a learner in learning and practice environments. There must be mechanisms in place for designated prescribing practitioners to liaise with course providers regularly about the progress of a pharmacist independent prescriber in training in learning and practice environments.

Domain 4 – Monitoring, review and evaluation

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

Criteria to meet this standard

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

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

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

4.4 Course monitoring and review must take into account the health and care environment to ensure that courses remain up-to-date and reflect current practice.

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

4.6 The providing institution must have validated the course before applying for GPhC accreditation.
Domain 5 – Course design and delivery

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

**Criteria to meet this standard**

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

5.2 Courses must be designed and delivered in a way which integrates and builds on the pre-existing knowledge, skills and practice of pharmacists in training as pharmacist independent prescribers.

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

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

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

5.6 Pharmacist independent prescribers in training must only undertake tasks in which they are competent, or are learning to be competent under supervision, so that patient safety is not compromised.

5.7 Pharmacist independent prescribers in training must be supervised using agreed mechanisms in all clinical practice environments to ensure safe person-centred care is delivered at all times.

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

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

5.10 Causes for concern about a pharmacist independent prescriber in training, designated prescribing practitioners or the learning environment must be addressed as soon as possible and in such a way that the cause for concern is dealt with.
Domain 6 – Learning in practice

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

**Criteria to meet this standard**

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

6.2 In the learning in practice settings identified in 6.1, pharmacist independent prescribers in training will prescribe under the supervision of a designated prescribing practitioner.

6.3 If more than one person is involved in the supervising a pharmacist independent prescriber in training, one independent prescriber must assume primary responsibility for their supervision. That person will be the designated prescribing practitioner for the pharmacist independent prescriber in training.

6.4 Course providers must approve the designated prescribing practitioner and agree that they have the core competencies to carry out the role effectively.

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

Domain 7 – Assessment

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

**Criteria to meet this standard**

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

7.2 Course providers are responsible for ensuring that all learning outcomes are assessed fully, using appropriate methods, and that teaching and learning is aligned with assessment.
7.3 Patient safety must be paramount at all times, and the assessment strategy must assess whether a pharmacist independent prescriber in training is practising safely.

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

7.5 Agreements must be in place between course providers and designated prescribing practitioners that describe the roles and responsibilities in the assessment of pharmacist independent prescribers in training.

7.6 Assessments must be carried out by appropriately trained and qualified people who are competent to assess the performance of pharmacist independent prescribers in training.

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

7.8 Pharmacist independent prescribers in training must receive regular, appropriate and timely feedback on their performance to support their development as learners.

7.9 Assessment regulations must be appropriate for a course that leads to professional annotation. On completion of the course, pharmacist independent prescribers must demonstrate that their practice is safe and prioritises patient safety.

7.10 Pharmacist independent prescribers in training must pass all summative assessments before being signed off.

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

**Domain 8 – Support and the learning experience**

**Standard 8: Pharmacist independent prescribers in training must be supported in all learning environments to develop as learners during their training.**

**Criteria to meet this standard**

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

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

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

8.3 There must be clear procedures for pharmacist independent prescribers in training to raise concerns. Any concerns must be dealt with promptly, with documented action taken where appropriate.

8.4 Everyone supporting pharmacist independent prescribers in training must take into account the GPhC’s Guidance on tutoring for pharmacists and pharmacy technicians in their work as appropriate.

Domain 9 - Designated prescribing practitioners

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

Criteria to meet this standard

9.1 Course providers must have appropriate mechanisms for ensuring that designated prescribing practitioners are fit to be the supervisors of pharmacist independent prescribers in training.

9.2 Prospective designated prescribing practitioners must have:

- active prescribing competence applicable to the areas in which they will be supervising;
- appropriate patient facing clinical and diagnostic skills;
- supported or supervised other healthcare professionals; and
- the ability to assess patient facing clinical and diagnostic skills.

9.3 Course providers must provide training for designated prescribing practitioners on:

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

9.4 Course providers must support designated prescribing practitioners when they are acting in that role.

9.5 Course providers must provide designated prescribing practitioners with feedback about their performance as prescribing supervisors and arrange extra training, support and development as necessary.
1. Aims and purpose of the project/policy

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

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

- Changing the practice supervision requirements to allow non-medical independent prescribers, as well as doctors, to supervise pharmacists in training to become independent prescribers; and
- Removing the pre-requisite entry requirement that pharmacists must have two years’ experience of working with patients before they can apply for an independent prescribing programme (following consultation this will not be implemented in full)
1.3 Domain 2 of our revised standards includes a separate domain dedicated to equality and diversity. This aims to ensure that course developers and providers consider and promote equality and diversity and use equality and diversity data to inform and influence the design and delivery of their courses.

1.4 The EIA aims to help ensure that our future standards do not unfairly affect groups with protected characteristics. It focuses on how protected characteristics have been considered in the standards development process and especially through our stakeholder engagement. In carrying out this analysis, we have considered the potential equality and diversity implications of the revised standards.

1.5 We aim to be proactive in facilitating opportunities for people with the widest possible range of experience and perspectives to engage with our work, and by doing so to ensure that we are not acting in a way that is incompatible with a Convention right and meeting our Public Sector Equality Duty under the Equality Act 2010. To meet Section 149 of the Equality Act 2010 we have due regard to each of the following statutory objectives:

- Eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
- Advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it; and
- Foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

1.6 In preparing this analysis, we have considered all of the statutory objectives under Section 149 of the Equality Act 2010.

1.7 The EIA includes an overview of the work we have completed to inform our understanding of the equality and diversity dimensions of the proposed changes. We aimed to identify any trends or issues that apply to people who share protected characteristics and considered potential negative impacts on these groups.

1.8 The EIA has been informed by our quantitative and qualitative analysis of responses to the consultation; the available data and/or evidence relating to groups of people with protected characteristics; and, our extensive engagement with a wide variety of stakeholders through stakeholder events and patient focus groups held across all four countries (England, Wales, Scotland and Northern Ireland) during April and May 2018. The analysis assists Council to consider whether the changes to the standards should be approved and/or be subject to further amendment before introduction.

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

2 The Human Rights Act 1998, Section 6f.

3 The Equality Act 2010, Section 149.
1.9 We sought to identify and mitigate any adverse impact on groups of people with a protected characteristic. This includes future pharmacist independent prescribers, people involved in their education and patients or members of the public interacting with them and using their services.

**Policy context**

1.10 The delivery of healthcare has been changing quickly in response to the needs of a changing population. The population is increasing and getting older, with health needs that are getting more complicated. This is adding to the demands on, and the cost of, national health services. Governments across the UK have highlighted the need for the healthcare workforce to develop and adapt to meet these demands, and this includes the pharmacy workforce.

1.11 Government policies across the UK have specifically highlighted the important role of pharmacists in general and the importance of non-medical prescribing. Doctors/dentists/veterinary surgeons used to be the only healthcare professionals allowed to prescribe. The 1999 Crown Review proposed that as pharmacists and nurses had an appropriate level of knowledge and skills they should be allowed to prescribe medicine. This recommendation was accepted by government and by 2003 pharmacist supplementary prescribing was allowed. By 2006 pharmacist independent prescribing was also allowed.

1.12 Independent prescribing allows prescribers to prescribe without consulting another prescriber, whereas supplementary prescribing only allows prescribers to prescribe within a patient-specific clinical management plan drawn up by another prescriber, usually a doctor.

1.13 The Royal Pharmaceutical Society of Great Britain (RPSGB), then the regulator for pharmacists in Great Britain (GB), defined the education and training that pharmacist prescribers would need, based on broad guidelines from the Department of Health (DH). The RPSGB began to accredit courses that would lead to pharmacists having an ‘annotation’ on its register as either a supplementary or an independent prescriber.

1.14 Interest in supplementary prescribing has decreased sharply over the years and we are no longer accrediting courses. We accredit a small number of conversion courses to independent prescribing. The current review only focuses on pharmacist independent prescribing because all the signs show that it is the independent role not the supplementary one that will grow in the future. The number of pharmacist independent prescribing courses continues to increase. There are now 50 accredited independent prescribing courses in the UK\(^4\) open to pharmacists.

1.15 Governments across the UK encourage pharmacists to train and practise as pharmacist independent prescribers. The different countries' governments' healthcare agendas and funding priorities have influenced trend in applicants and workplaces in their respective countries. The Northern Irish Government committed to increase the number of pharmacist independent prescribers in GP practices and provided the associated funding to support that commitment\(^5\). Similarly, both the English and Scottish Governments have highlighted how independent prescribing can contribute to public health.

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\(^4\) As of 11.09.18 we accredit 50 IP courses-including four under provisional approval and two conversion courses.

\(^5\) The former Minister of Health in the Northern Ireland Government announced in 2015 a five-year initiative to increase the number of pharmacists in GP practices. [Minister announces investment to put pharmacists in GP practices](http://example.com), Northern Ireland Government, December 2015.
and provided support to increase the number of healthcare professionals training as an independent prescriber.\(^6\)

1.16 Prior to consulting on new standards, we issued a discussion paper on the supervision of pharmacist prescribers in training. This consultation sought feedback on the proposal to change the practice supervision requirements to allow non-medical independent prescribers to supervise pharmacists training to become independent prescribers. This initial consultation ran between November and February 2017.\(^7\) We sent the discussion papers to other health professional regulators (particularly those who regulate prescribers), funders of health education and training, professional representative bodies, employers, education and training providers, and patients’ representative bodies.

1.17 We analysed the discussion paper responses\(^8\) and conducted further stakeholder engagement\(^9\), incorporated comments in our revised standards before we launch a consultation on our revised standards for the education and training of pharmacist independent prescribers.

1.18 One key change to note is that, after reviewing the responses to the consultation, we have agreed not to implement the proposed change to entry requirements in full. However, we will continue with the introduction of a requirement to provide evidence of appropriate experience to train as an independent prescriber.

1.19 Once the standards are approved, we will take steps to engage with course providers and prepare to accredit and quality assure courses leading to annotation. As part of the accreditation and quality assurance process, course providers are responsible for providing evidence showing how they meet or apply each of our standards to gain accreditation. This is one of the ways we assure the implementation of the new standards, including standards specifically focusing on equality and diversity aspects.

1.20 We will also be producing a supporting evidence framework which will provide practical examples for course designers and developers about the type of evidence that could be provided through the accreditation process. This document will also assist in ensuring consistent interpretation of the new standards. To inform this process, in June 2018 we contacted all the 42 independent prescribing course leads to request examples of suitable evidence (including thumbnail sketches of suitably qualified applicants) which they use when evaluating independent prescribing course applications. We received some rich qualitative responses, which are illustrated in a summary report, and will inform the future developed evidence framework document.\(^10\)

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\(^{6}\) To support the implementation of NHS England’s Five Year Forward View, the English Government has created a Pharmacy Integration Fund to support one of the English Government’s priorities to deploy more clinical pharmacists and pharmacy services in community and primary care including groups of general practices, care homes and urgent care settings. The Scottish Government also published their report, Prescription for Excellence, in 2016 as well as the revised version in 2017, Achieving Excellence in Pharmaceutical Care which set out their vision of pharmacy in the future, including an increase in independent prescribing roles for pharmacists.

\(^{7}\) GPhC seeks views on supervising independent prescribers in training

\(^{8}\) Supervising pharmacist independent prescribers in training: Summary of responses to the discussion paper

\(^{9}\) Standards for the education and training of pharmacist independent prescribers, Summary of findings: independent prescriber pre-consultation engagement

\(^{10}\) Summary report IP course provider feedback-DB-11.07.18-V.1.1
1.21 In addition, as part of the monitoring of the implementation of the standards we are also committed to a review our quality assurance and accreditation process.

2. Review of available information and/or data

Developing our evidence-base

2.1 We have carried out a systematic and evidence-based approach to our policy development, including an assessment of the equality and diversity dimensions of our proposals.

2.2 Through our evidence gathering we have identified certain areas where it would be beneficial to gather more evidence and data to inform policy development, as there are gaps in comparison to the data we collect on future pharmacists. As the annotation of prescribers on our register is relatively new, the available data in relation to equality and diversity indicators has been limited.

Legal framework

2.3 Article 44(1)(a) of the Pharmacy Order 2010 provides that the Council must

(a) determine:

(i) programmes or courses in respect of, or any combination of, education, training or experience required in order to obtain an annotation in respect of a specialisation,
(ii) the amount and type of education, training and experience required in order to obtain an annotation in respect of a specialisation,

2.4 Article 4(3) sets the principal functions of the Council. In regard to education it is role is:

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

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

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

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

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

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

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

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

2.8 Finally, Article 42(7) states that:

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

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

2.9 In developing the standards, we also gave due regard to our statutory objectives under Section 149 of the Equality Act 2010 and we believe that the proposals align with our overarching legal objective which is the protection of the public11.

Other standards which pharmacist independent prescribers have to adhere to

2.10 It is important to note that pharmacist independent prescribers have to adhere to other standards because of their registration as pharmacists. Standard 1 on person centred-care of our Standards for Pharmacy Professionals (2017), states that everyone has the right to be treated with fairness, dignity

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11 The Pharmacy Order 2010, Article 6(1).
and respect and this includes respect for a person’s religion or belief, and respect for the rights of others.

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

Pharmacist independent prescriber data

GPhC commissioned surveys and reports

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

- GPhC Registrant survey 201312,
- Prescribers Survey Report (2016)13, and
- GPhC Register Analysis 2011 (Pharmacists)14.

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

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

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

2.15 The information on our register enables us to understand the demographic make-up of the current pharmacist independent prescriber group. On 29th August 201815, there were 6,019 annotated independent prescribers, including 981 of these pharmacists with dual independent and supplementary prescribing annotations. There were 334 annotated supplementary prescribers.

2.16 Since 2010, the number of annotated pharmacist independent prescribers has steadily increased from 1,545 in 2010 to 6,019 in 201816. In part, this is due to the relative decline in the number of supplementary prescribers, 1,431 in 2011 to 334 in 2018, as all accredited courses for supplementary prescribers stopped by the end of 200917. As it was no longer possible to train as a supplementary prescriber, pharmacists trained as independent prescribers instead, or applied for a conversion course to become independent prescribers. As such, the number of pharmacists annotated as both a supplementary and independent prescriber has remained relatively stable between 2011 and 2018.

12 The GPhC Registrant survey (2013)
13 Prescribers Survey Report (2016)
14 GPhC Register Analysis (2011)
15 Obtained from data and insight team-data set extract as of 29.08.18 at 22:00.
16 GPhC Register analysis, 2011 and 2018 CRM data.
17 GPhC Register analysis, 2011
2.17 There are limits to the data we currently collect on sexual orientation, gender reassignment, marriage/civil partnership, pregnancy/maternity. As a result, we recently modified our Equalities Monitoring Form to collect further protected characteristics data from pharmacist independent prescribers registering with us to address this gap.

Age

2.18 45.4% of pharmacist independent prescribers on our register are aged between 30 and 39 years old and more than a third of the pharmacist independent prescribers on our register are between 40 and 54 (38 per cent)\(^\text{18}\).

<table>
<thead>
<tr>
<th>Age</th>
<th>Number of IPs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-29</td>
<td>624</td>
<td>8.8%</td>
</tr>
<tr>
<td>30-34</td>
<td>1,579</td>
<td>22.4%</td>
</tr>
<tr>
<td>35-39</td>
<td>1,624</td>
<td>23.0%</td>
</tr>
<tr>
<td>40-44</td>
<td>1,183</td>
<td>16.8%</td>
</tr>
<tr>
<td>45-49</td>
<td>838</td>
<td>11.9%</td>
</tr>
<tr>
<td>50-54</td>
<td>656</td>
<td>9.3%</td>
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<tr>
<td>55-59</td>
<td>352</td>
<td>5.0%</td>
</tr>
<tr>
<td>60-64</td>
<td>167</td>
<td>2.4%</td>
</tr>
<tr>
<td>65+</td>
<td>31</td>
<td>0.4%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>7,054</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

2.19 In 2011, the pharmacist independent prescribers on our register aged between 30-49 made up 78.1 per cent of the annotated registrants. In comparison, in 2018, the pharmacist independent prescribers on our register aged between 30-49 made up 74.1 per cent of annotated registrants. This is only a drop of four points, but indicates there is a relative stability in the most predominant age band of our annotated registrants. We repeatedly heard from course providers during our pre-consultation engagement that they are receiving increased applications from more recent graduates, as opposed to previously where it was predominantly more experienced registrants.

Disability

2.20 In 2018, the proportion of pharmacist independent prescribers on our register who stated they did not have a disability was 27.5%. Those that stated they do have a disability were 0.2%. However, 72.% of pharmacist independent prescribers on our register did not respond to this question.\(^\text{19}\)

<table>
<thead>
<tr>
<th>Do you consider yourself to have a disability</th>
<th>Number of IPs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>13</td>
<td>0.2%</td>
</tr>
<tr>
<td>No</td>
<td>1,939</td>
<td>27.5%</td>
</tr>
</tbody>
</table>

\(^\text{18}\) This data and the corresponding table extract is from CRM data as at 10/09/2018 22:00. We also have protected characteristic data for supplementary prescribers but are focusing on independent prescribers in this EIA as we are no longer accrediting supplementary prescribing courses.

\(^\text{19}\) This data and the corresponding table extract is from CRM data as at 10/09/2018.
<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Number of IPS</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not provided</td>
<td>5,102</td>
<td>72.3%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>7,054</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Number of IPS</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Asian - Other</td>
<td>156</td>
<td>2.2%</td>
</tr>
<tr>
<td>Bangladeshi</td>
<td>58</td>
<td>0.8%</td>
</tr>
<tr>
<td>Black - African</td>
<td>279</td>
<td>4.0%</td>
</tr>
<tr>
<td>Black - Caribbean</td>
<td>19</td>
<td>0.3%</td>
</tr>
<tr>
<td>Black - Other</td>
<td>12</td>
<td>0.2%</td>
</tr>
<tr>
<td>Chinese / Chinese British</td>
<td>159</td>
<td>2.3%</td>
</tr>
<tr>
<td>Indian</td>
<td>1,018</td>
<td>14.4%</td>
</tr>
<tr>
<td>Not Supplied</td>
<td>590</td>
<td>8.4%</td>
</tr>
<tr>
<td>Other Ethnic Group</td>
<td>142</td>
<td>2.0%</td>
</tr>
<tr>
<td>Other Mixed</td>
<td>34</td>
<td>0.5%</td>
</tr>
<tr>
<td>Pakistani</td>
<td>518</td>
<td>7.3%</td>
</tr>
<tr>
<td>White - British</td>
<td>3,612</td>
<td>51.2%</td>
</tr>
<tr>
<td>White - Irish</td>
<td>158</td>
<td>2.2%</td>
</tr>
<tr>
<td>White - Other</td>
<td>256</td>
<td>3.6%</td>
</tr>
<tr>
<td>White and Asian</td>
<td>28</td>
<td>0.4%</td>
</tr>
<tr>
<td>White and Black African</td>
<td>8</td>
<td>0.1%</td>
</tr>
<tr>
<td>White and Black Caribbean</td>
<td>7</td>
<td>0.1%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>7,054</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

2.21 In 2011, the vast majority of pharmacist independent prescribers described themselves as ‘White’ (British, Irish and other) accounting for 80.1%20. In comparison, in 2018, those who described themselves as ‘White’ (British, Irish and other) accounted for 57%21. This is a decrease in 23 points between 2011 and 2018 in pharmacist independent prescribers who described themselves as ‘White’. In 2018, the pharmacist independent prescribers who described themselves as ‘Asian’ (Other, Bangladeshi, Indian, Pakistani) accounted for 24.7%. Only 4.5% of pharmacist independent prescribers on our register described themselves as ‘Black’.

**Sex**

2.22 Two thirds of the pharmacist independent prescribers on our register (67.5%) are women22.

2.23 The gender breakdown of pharmacist independent prescribers has remained stable between 2011 and 2018. In 2011, pharmacist independent prescribers were 69% female, whereas in 2018, this reduced...
slightly to 67.5%\textsuperscript{23}, whereas during the same time period, male pharmacist independent prescribers increased slightly from 31% in 2011 to 32.5% in 2018\textsuperscript{24}.

<table>
<thead>
<tr>
<th>Gender</th>
<th>Number of IPs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>4,759</td>
<td>67.5%</td>
</tr>
<tr>
<td>Male</td>
<td>2,295</td>
<td>32.5%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>7,054</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

**Religion**

2.24 In 2018, we recorded the religion of so few pharmacist independent prescribers on our register that it makes little sense to draw conclusions from the data we have on religion. 76.3% of the pharmacist independent prescribers on our register did not respond to this question. From the 19% that did provide their religion, 8.7% identify as Christians, 6.3% as Muslim and 4.7% stated they did not have a religion\textsuperscript{25}.

<table>
<thead>
<tr>
<th>Religion</th>
<th>Number of IPs</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Buddhist</td>
<td>11</td>
<td>0.2%</td>
</tr>
<tr>
<td>Christian</td>
<td>611</td>
<td>8.7%</td>
</tr>
<tr>
<td>Hindu</td>
<td>170</td>
<td>2.4%</td>
</tr>
<tr>
<td>Jewish</td>
<td>4</td>
<td>0.1%</td>
</tr>
<tr>
<td>Muslim</td>
<td>447</td>
<td>6.3%</td>
</tr>
<tr>
<td>None</td>
<td>329</td>
<td>4.7%</td>
</tr>
<tr>
<td>Other</td>
<td>29</td>
<td>0.4%</td>
</tr>
<tr>
<td>Sikh</td>
<td>73</td>
<td>1.0%</td>
</tr>
<tr>
<td>Not provided</td>
<td>5,380</td>
<td>76.3%</td>
</tr>
<tr>
<td>Grand Total</td>
<td>7,054</td>
<td>100.0%</td>
</tr>
</tbody>
</table>

\textsuperscript{23} This data and the corresponding table extract is from CRM data as at 10/09/2018 22:00.
\textsuperscript{24} GPhC Register analysis, 2011 CRM data.
\textsuperscript{25} This data and the corresponding table extract is from CRM data as at 10/09/2018 22:00.
3. Screening for relevance to equality and diversity issues

<table>
<thead>
<tr>
<th>Does this project/policy have significant/disproportionate? relevance to</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Disability</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Gender reassignment</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Marriage and civil partnership</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Pregnancy and maternity</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Race</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Religion or belief</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Sex</td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>Sexual orientation</td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

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

4.1 Yes, a full EIA required.

4.2 We ticked categories in the screening table where we had evidence of a strong likelihood of disproportionate impact. However, we recognise that, although there may be impacts on other protected characteristics, the evidence gathered suggests there would not be a disproportionate impact on people with those protected characteristics. The standards and evidence framework, monitored through our accreditation and quality assurance processes will assess evidence arising about any equality and diversity related impacts.

5. Date and method of consultation

Pre-consultation engagement

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

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

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

5.3 As part of the discussion document survey, we have included a question about equality and diversity (Question 16: “Are there any equality, diversity or inclusion issues you think have been raised by our proposals?”) to ensure that we captured any issues that respondents wish to raise. We analysed the responses provided by stakeholders to Question 16 of the survey.

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

• 526 respondents (91%) did not think there was anything in the standards or suggested changes to the criteria for registration that disproportionately affected any particular group over others
• 11 respondents (2%) did not comment that question, and
• 40 respondents (7%) felt that our proposed changes would disproportionately affect particular groups over others

5.5 Only five respondents raised equality and diversity issues. Their main comments focused on:

• The need to have a strong focus on equality and diversity in the standards; and
• The need for monitoring equality and diversity issues of both pharmacists and training in practice supervisors.

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

5.7 The findings of this work were presented to the independent prescribing expert advisory group on 15 January 2018 and the potential impact of the proposals were considered as part of the drafting and pre-consultation process.
Formal consultation and focus group

5.8 We formally consulted on the standards between 14 March 2016 and 6 June 2018 (12-week consultation). As part of the consultation survey, we included four questions about equality and diversity:

5.9 In total, we received written responses from 59 organisations and 340 individuals to the consultation survey. From these 399 responses to the online survey all answered the equality and diversity questions:

- 301 respondents (75%) did not think there was anything in the standards or proposed changes that would disproportionately affect any particular group over others;
- 70 respondents (18%) did not comment on that question; and
- 28 respondents (7%) felt that our standards or proposed changes would disproportionately affect particular groups over others. Many of these comments referred to groups which did not have protected characteristics, for example, employers or those working in community pharmacy.

5.10 We also received an additional four long narrative responses which have also been analysed independently to the responses to the consultation survey.

5.11 We analysed the responses provided by stakeholders to Questions 11 and 11b and 12 and 12b of the consultation survey. These are integrated in section seven of the EIA (full impact assessment).

5.12 We do not hold any data on the proportion of individual respondents to the consultation who were pharmacist independent prescribers. This means we unable to determine whether respondents to our consultation were representative of the population of pharmacist independent prescribers.

Equality characteristics of consultation respondents

The equality monitoring questions in the consultation were optional to answer and not compulsory. 282 individual respondents of the 340 who responded to the consultation answered these questions, though not all respondents answered every question. The overwhelming majority of individual responses to the consultation identified themselves as pharmacists (330 out of 340).

Age:

<table>
<thead>
<tr>
<th>Age (years)</th>
<th>Percentage of responded to consultation in category (all respondents)**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under 25*</td>
<td>3.7%</td>
</tr>
<tr>
<td>25-34</td>
<td>26.9%</td>
</tr>
<tr>
<td>35-44</td>
<td>25.0%</td>
</tr>
</tbody>
</table>

26 Question 11 asked: “Do you think anything in the standards or proposed changes would impact - positively or negatively - on certain individuals or groups who share any of the protected characteristics listed above?” Question 11a asked: Please describe the impact and the individuals or groups concerned”. Question 12 asked “Do you think anything in the standards or proposed changes would impact - positively or negatively - on any other individuals or groups”? Question 12a asked: “Please describe the impact and the other individuals or groups concerned” to ensure that we captured any issues that respondents raise”. 
<table>
<thead>
<tr>
<th>Age Group</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>45-54</td>
<td>20.9%</td>
</tr>
<tr>
<td>55-64</td>
<td>12.3%</td>
</tr>
<tr>
<td>65+</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

* No IPs on our register currently are aged under 25
** Not all respondents gave their age

5.13 Disability

<table>
<thead>
<tr>
<th>Disability</th>
<th>Percentage of responded to consultation in category (all respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Consider self to be disabled</td>
<td>1.5%</td>
</tr>
<tr>
<td>Do not consider self to be disabled</td>
<td>90.2%</td>
</tr>
<tr>
<td>Prefer not to say</td>
<td>8.3%</td>
</tr>
</tbody>
</table>

5.14 Ethnicity

<table>
<thead>
<tr>
<th>Ethnicity</th>
<th>Percentage of responded to consultation in category (all respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>White (British; Irish; other white)</td>
<td>52.8%</td>
</tr>
<tr>
<td>Asian (Bangladeshi; Indian; Pakistani, Other)</td>
<td>22.1%</td>
</tr>
<tr>
<td>Black (African; Caribbean; other)</td>
<td>7.5%</td>
</tr>
<tr>
<td>Other ethnicity</td>
<td>3.7%</td>
</tr>
<tr>
<td>Not disclosed</td>
<td>12%</td>
</tr>
</tbody>
</table>

5.15 Gender/Sex

<table>
<thead>
<tr>
<th>Gender</th>
<th>Percentage of responded to consultation in category (all respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>52.2%</td>
</tr>
<tr>
<td>Male</td>
<td>39.9%</td>
</tr>
<tr>
<td>Not disclosed</td>
<td>7.5%</td>
</tr>
</tbody>
</table>
### 5.16

**Religion**

<table>
<thead>
<tr>
<th>Religion</th>
<th>Percentage of responded to consultation in category (all respondents)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Christian</td>
<td>36.3%</td>
</tr>
<tr>
<td>Muslim</td>
<td>13.1%</td>
</tr>
<tr>
<td>Other religion</td>
<td>4.1%</td>
</tr>
<tr>
<td>No religion</td>
<td>21.3%</td>
</tr>
<tr>
<td>Not disclosed</td>
<td>16.1%</td>
</tr>
</tbody>
</table>

5.17 Due to the lack of data about how many of the respondents were independent prescribers, we cannot draw any conclusions here in relation to how representative the responses are of this group as a whole.

5.18 In addition to launching the consultation paper\(^{27}\), we consulted directly with an extensive list of relevant stakeholders. These meetings were attended by a diverse mix of groups and organisations representing the pharmacy sector.\(^{28}\)

5.19 We also held stakeholder events and patient focus groups which allowed us to discuss the consultation questions in more depth with patients, members of the public and course providers. The list of all the engagements events held are listed below:

- Stakeholder events (held in Cardiff, London and Aberdeen)
- Patient focus groups (held in Glasgow, Cardiff and London)
- Edinburgh NHS Education Scotland (NES) Conference and Meeting with NES
- Meeting with RPS, and
- Meeting with Chief Pharmaceutical Officer, Scottish Government.

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\(^{27}\) Consultation on standards for the education and training of pharmacist independent prescribers.

\(^{28}\) This included representatives from professional membership bodies for pharmacists and pharmacy technicians, multiples and independent pharmacies, education and training, NHS organisations, public health organisations, community and hospital pharmacy, and other stakeholders.
6. Give a brief summary of the results of the consultation/involvement. How have these affected the proposal?

6.1 Please refer to our analysis of discussion paper responses and stakeholder engagement meetings for details of the outcomes\(^{29}\). Please refer to our analysis of consultation responses for details of the outcomes\(^{30}\).

6.2 All issues relating to equality and diversity identified through the engagement and consultation process have been set out in detail in Section 7 below (full impact assessment).

6.3 The consultation we conducted from March 2018 to June 2018 entailed specific questions about any perceived potential disproportionate impact of our proposed changes on any particular groups (questions 11 and 12).

6.4 We heard from some participants from our engagement events\(^{31}\) that it was down to course providers to ensure that they consider the impact that their independent prescribing courses may have on people with protected characteristics, during the time they develop their respective courses.

6.5 Following the report of the consultation, Council agreed not to remove of the requirement for two years’ experience before entering an independent prescribing course. While respondents to the consultation generally supported the introducing strengthened entry requirements, many said they should be combined with (not replace) the two-year requirement. We have followed this suggestion.

7. Full impact assessment

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

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

Trends in the age profile of pharmacist independent prescribers

7.1 Different age groups have distinct healthcare and education needs and concerns. As part of our research and engagement activity, we have sought to assess the impact of our proposals on people of different ages. As the age of trainees is spread across a wide age range, it is important that education and training is sufficiently flexible to allow trainees to fit in with their work, family and other personal commitments.

7.2 Mitigation: As the age of pharmacist independent prescribers in learning is spread across a wide age range, it is important that education and training is sufficiently flexible to allow trainees to fit in with

\(^{29}\) Supervising pharmacist independent prescribers in training: Summary of responses to the discussion paper and Standards for the education and training of pharmacist independent prescribers and the Summary of findings: independent prescriber pre-consultation engagement.

\(^{30}\) Standards for the education and training standards of pharmacist independent prescribers: Consultation report

\(^{31}\) London stakeholder engagement event.
their work, family and other personal commitments and our standards emphasise this. We have adopted an outcomes-focused approach throughout the standards to encourage flexibility in the design and mode of delivery, which can be face-to-face, at a distance, online or a combination of these. This flexibility allows course developers and course providers to be responsive to the needs of the trainees they are seeking to attract.

**Disability – consider environmental, social and attitudinal barriers**

7.3 People with disabilities face many barriers in accessing healthcare and education. As part of our research and engagement activity, we have sought to assess the impact of our proposals on people with disabilities.

**Impact on all proposed changes to our standards - general feedback**

7.4 We heard anecdotal feedback from patient focus group participants who thought that the proposals and drive to increase the pool of pharmacist independent prescribers was potentially a positive impact on people living with disabilities, as it could create a wider range of access to medical services. One example given, was if people who are disabled are travelling away from their regular pharmacy or GP practice, and need access to medical advice or medication whilst away, they may be able to do so more easily.

**Conclusion**

7.5 There is very little feedback to suggest impacts from our proposals on those with disabilities. In the feedback we did receive, there are mixed views about the potential impact our standards and proposals could have on people with disabilities.

**Mitigation**

7.6 Equality and diversity are embedded in the standards, and forms Standard 2 for course providers. Criterion to meet Standard 2 states “equality and diversity data must be used when designing and delivering courses and the learning experience”; and that “reasonable adjustments must be made to course delivery to help pharmacist independent prescribers in training with specific needs to meet the learning outcomes”. The same principle applies to the application process, which we state must ‘meet relevant legislation’ in standard 1.2. This includes making reasonable adjustments to enable students to provide evidence of appropriate experience as part of an application process.

7.7 We aim to ensure that the standards we set do not negatively impact on people with disabilities. All learning environments are required to comply with the Equalities Act 2010 and course providers and employers must ensure that there are no barriers to those who require a reasonable adjustment during their training.

7.8 Course providers should make sure staff are aware that certain trainees have more difficulty in adapting to specific teaching and training approach and encourage staff to undertake a more proactive approach to ensure all trainees benefit from their teaching and training. Course providers are required

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32 Cardiff patient focus group.
to have a teaching and learning strategy which directly links to the assessment strategy, which should outline the approach to reasonable adjustments.

7.9 We encourage course providers to look at ways to improve the feedback they provide and to actively use the feedback they receive from trainees. As part of their teaching and learning strategy, course providers should consider and report to us demonstrating how the learning outcomes in Part 1 of the standards will be applied and achieved.

7.10 To support this, the evidence framework will also provide further information and clarity to course providers to help them understand how equality and diversity must be embedded in their course design and delivery. In addition, the evidence framework will provide clarity for course providers about how they may choose to meet the standards in relation to reasonable adjustments. This should ensure that course applicants are not unfairly disadvantaged and course providers are explicitly aware and informed of their responsibilities in the design and delivery of the course.

7.11 We will also review our quality assurance processes for accredited and recognised programmes and consider in this review how evidence requirements for course providers to demonstrate how they support students with disabilities can be strengthened.

7.12 Implementation of Standard 2 will be monitored by our quality assurance process. We will monitor feedback during implementation to ensure that no negative impacts arise that have not been identified and need to be mitigated in the future.

<table>
<thead>
<tr>
<th>Gender reassignment – consider impact on transsexual and transgender people including bullying, harassment and discrimination issues not least ensuring privacy of data to avoid disclosure of gender history</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.13 We do not have evidence to suggest any disproportionate impact of the proposals in relation to gender reassignment.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Marriage or Civil Partnership – consider impact on married people or people in a civil partnership, young or old</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.14 We do not have evidence to suggest any disproportionate impact of the proposals in relation to marriage or civil partnership.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pregnancy or maternity – consider impact on pregnant women and those on maternity leave</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.15 As part of our research and engagement activity, we have sought to assess the impact of our proposals on pregnant women and those on maternity leave. Some of the respondents to the consultation raised the possibility of discrimination on the grounds of pregnancy or maternity in selection processes. We expect selection processes to be fair and unbiased, and this is reflected in specific parts of the standards.</td>
</tr>
<tr>
<td>7.16 Respondents also suggest that pharmacists who take maternity or paternity leave could be negatively impacted if they wish to train as an independent prescriber. This is because it may jeopardise them building up enough suitable /relevant experience. They will have accumulated less overall prescribing experience compared to those who do not have children or childcare responsibilities. Parents could then be additionally negatively impacted, as they will be hindered from acquiring further experience, due to managing childcare responsibilities.</td>
</tr>
</tbody>
</table>
7.17 Participants from our engagement events shared the views expressed above\textsuperscript{33}. They informed us that course providers do not accept pharmacists onto independent prescribing courses whilst on maternity leave, as it would leave a gap in their practice. Respondents explained that these pharmacists are currently able to put their pharmacist independent prescribing course on hold during maternity leave. Course providers do not allow pharmacists to train whilst on maternity leave, because they are not practising during this time.

**Mitigation**

7.18 Equality and diversity are embedded in the standards, and forms Standard 2 for course providers. Criterion to meet Standard 2 states “equality and diversity data must be used when designing and delivering courses and the learning experience”; and that “reasonable adjustments must be made to course delivery to help pharmacist independent prescribers in training with specific needs to meet the learning outcomes”. The same principle applies to the application process, which we state must apply selection criteria ‘in an unbiased way’ and ‘meet relevant legislation’ in standard 1.2. This includes complying with legislation to ensure that selection processes are free of bias on the grounds of gender or maternity (and other protected characteristics).

7.19 We aimed to ensure that the standards we set did not negatively impact on pregnant women and those on maternity and paternity leave. All learning environments are required to comply with the Equalities Act 2010 and providers and employers must ensure that there are no barriers to those who require a reasonable adjustment during their training.

7.20 Course providers should make sure staff are aware of the fact that certain trainees have more difficulty in adapting to specific teaching and training approaches and encourage staff to undertake a proactive approach to ensure all trainees benefit from their teaching and training. Course providers are required to have a teaching and learning strategy which directly links to the assessment strategy, which should outline the approach to reasonable adjustments.

7.21 We encourage course providers to look at ways to improve the feedback they provide and to actively use the feedback they receive from trainees. As part of their teaching and learning strategy, course providers have to consider and report to us demonstrating how the learning outcomes in Part 1 of the standards will be applied and achieved.

7.22 To support this, the evidence framework will support Standard 2 and provide further information and clarity to course providers to help them understand how equality and diversity must be embedded in their course design and delivery. In addition, the evidence framework will also provide course providers with clarity about how they may choose to meet the standards in relation to reasonable adjustments. We could consider in our evidence framework how maternity provision is included, to acknowledge that some pharmacists will be away from practice for a period of time. This should ensure that course applicants are not unfairly disadvantaged and course providers are explicitly aware and informed of their responsibilities in the design and delivery of the course.

7.23 We will also review our quality assurance processes for accredited and recognised programmes and consider in this review how evidence requirements for course providers to demonstrate how they support students who are pregnant or taking maternity or paternity leave, can be strengthened.

\textsuperscript{33} London stakeholder engagement event.
7.24 Implementation of Standard 2 will be monitored by our quality assurance process. We will monitor feedback during implementation to ensure that no negative impacts arise that have not been identified and need to be mitigated in the future.

Race – consider impact on people of different ethnic groups, nationalities, gypsies, travellers, languages etc.

**Impact of the proposal to remove the two-year pre-requisite work experience requirement**

7.25 This proposal has since been withdrawn, although we will continue with the introduction of a requirement to provide evidence of appropriate experience to train as an independent prescriber.

7.26 Some organisational respondents suggested that BAME female pharmacists or pharmacist independent prescribers are over-represented in part-time and locum pharmacist roles, which means they could find it more difficult to access an independent prescribing qualification because they might be unable to accumulate sufficient relevant experience to apply to train as an independent prescriber. These respondents also suggested that, if the costs of courses rise, these groups will struggle disproportionately as they are more likely to self-fund their training or receive less support from an employer.

Conclusion

7.27 We need to look at ways to mitigate against these potential negative impacts on BAME female pharmacists. As mentioned before, in response to our proposed changes to our standards, if course providers have to increase their student fees, this could mean that BAME female pharmacists who are working in part-time roles or locum roles or when they do not necessary receive support from their employers, may find it more difficult to commence or complete an independent prescribing course.

Mitigation

7.28 Although we note this point, the costs of independent prescribing courses are outside of our control as a regulator. We will monitor feedback during implementation to ensure that no negative impacts arise that have not been identified and need to be mitigated in the future.

7.29 Please see section 7.44-7.45 below how the evidence framework will enable pharmacists from a range of sectors to demonstrate they meet criteria for entry to an independent prescribing course.

Religion or belief – consider impact on people with different religions or beliefs, or none

**Impact on all proposed changes to our standards - general feedback**

7.30 More generally, commenting on the impact of all the proposed changes to our standards, one consultation respondent suggested the ‘patient centred approach’ puts a great deal of pressure on pharmacist independent prescribers to go against their own religious beliefs, and sometimes it’s important to find the balance.

7.31 We heard from participants in our engagement events that they felt that some patients and members of the public, due to their beliefs, may feel more comfortable seeing their GP than a pharmacist independent prescriber, as they feel it is in a more private and confidential capacity.  

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34 Glasgow patient focus group.
7.32 One respondent raised a concern about coverage of certain topics if the designated prescribing practitioner holds a conscientious objection. However, this was based on a misunderstanding of our policy in this area and does not require further mitigation.

**Mitigation**

7.33 Our guidance on Religion, Personal Values and Beliefs addresses the single concern raised around conscientious objection and no further mitigation is necessary.

7.34 All pharmacist independent prescribers in learning are registered pharmacists, so need to adhere to and comply with our Standard for pharmacy professionals (May 2017), which underpins the above guidance.

7.35 We will monitor feedback during implementation to ensure that no negative impacts arise that have not been identified and need to be mitigated in the future.

### Sex – consider impact on men and women; working arrangements, for example, part-time, shift working, caring responsibilities

#### Impact on all proposed changes to our standards - general feedback

7.36 We heard some mixed views from participants in our engagement events regarding impacts of our proposed changes to our standards on both men and women (members of the public and patients).³⁵

7.37 Some participants believed that if all our proposals were introduced, there could be a positive impact especially on male patients and male members of the public. If more pharmacist independent prescribers are trained, this could mean that pharmacist independent prescribers could be more accessible than GPs to get appointments with. Participants thought that men in comparison to women, are often more reluctant to see their GP about health conditions, therefore with the option to see a pharmacist independent prescriber instead, it improves ease of access for men to obtain medical advice. Some participants also felt that it could help shift male attitudes to seeking medical advice.

7.38 Some participants believed that there could be a negative impact on women (patients and members of the public). Some female participants said they when it came to a personal health conditions they did not mind seeing either a male or female GP; because they trust they have appropriate level of medical training and competency in different medical situations. However, they said they do not have this similar confidence in the training or experience of pharmacist independent prescribers.

**Mitigation**

7.39 We will monitor feedback during implementation to ensure that no negative impacts arise that have not been identified and need to be mitigated in the future.

### Sexual Orientation – consider impact on bisexual, gay, heterosexual or lesbian

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

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³⁵ Cardiff patient focus group.
Other diversity and equalities-related issues

7.41 We have also considered the following equalities related issues. The main underlying themes have been summarised below, corresponding to the potential impacts against the different proposals.

Differences between hospital pharmacists and community pharmacists/community pharmacy

7.42 The feedback we received in organisational responses, stated it is important that course providers do not favour one sector over another (hospital or community), or put in place barriers which could result in pharmacists being unable to apply: this might apply more to community pharmacists without opportunities to gain relevant clinical experience.

7.43 The same respondents also felt it would be more difficult for community pharmacists in comparison to hospital pharmacists, to be able to successfully complete an independent prescribing programme as they are less likely to be working in multi-disciplinary teams

Mitigation

7.44 All course providers should have systems should be in place to enable pharmacists from all sectors to have the opportunity to apply, subject to a demonstration of competency. We will be producing a supporting evidence framework which will provide practical examples for course designers and developers about the type of evidence that could be provided through the accreditation process.

7.45 To inform this process, on 12th June 2018 we contacted all the independent prescribing course leads to request examples of suitable evidence (including thumbnail sketches of suitably qualified applicants) which they use when evaluating independent prescribing course applications. We received some rich qualitative responses, which are illustrated in a summary report, and will inform the future developed evidence framework document.36 This document will also assist in ensuring consistent interpretation of the new standards.

Differences between course providers

Impact of the proposal to remove the two-year pre-requisite work experience requirement and the Impact of the proposal to introduce new learning outcomes.

7.46 Some points made about this issue are no longer relevant as the proposal has been withdrawn. We will though continue with the introduction of a requirement to provide evidence of appropriate experience to train as an independent prescriber.

7.47 Participants from our engagement events requested that we provide robust guidance for course providers to assist them with the judgement on what is considered appropriate skills and experience to train as an independent prescriber, and to support course providers with the implementation of the proposals37.

Mitigation

7.48 We informed participants during the engagement events that we would in due course be producing an evidence framework to support course providers to see what consideration criteria will be deemed

36 Summary report-independent prescriber course provider feedback-DB-11.07.18-V.1.1
37 Questions participants asked were: a) how should course providers measure skill and experience on entry; b) what direction can be provided regarding the ‘pre-requisites’ to independent prescribing courses; c) which type of applicants are suitable to undertake an independent prescribing course, and d) how to define ‘sufficient experience’?
acceptable for entry onto an independent prescribing course. We are proposing the onus to be on course providers to ensure the quality of the independent prescribing courses they deliver.

7.49 To inform the evidence framework we conducted some qualitative research. We requested examples of suitable and unsuitable evidence which course providers use when evaluating independent prescribing applications. The aim is to incorporate these findings into development of the evidence framework which will act as the supporting guidance to the standards.

**Hurdles to becoming Designated Prescriber Practitioner (DPPs)**

**Impact of the proposal to extend the supervision of pharmacist prescribers in training to non-medical independent prescribers in practice as well as designated medical practitioners (DMPs)**

7.50 We received some positive feedback about our proposals to extend the supervision of pharmacist prescribers in training to all independent prescribers in practice. A few consultation respondents said it will provide greater flexibility to supervision, and also alleviate the pressure (burden) on GPs who are also Designated Medical Practitioners (DMPs). They said that DMPs in some situations are the most appropriate person to supervise trainee pharmacist independent prescribers.38 The benefits of extending the supervision of pharmacist prescribers in training could be an upskilled profession and potentially freeing up medical practitioners who would no longer be required to sign off all trainee prescribers.

7.51 A few consultation respondents said that our proposals to extend the supervision of pharmacist prescribers in training and introducing Designated Prescribing Practitioners (DPPs) could be jeopardised, because they believe many pharmacist independent prescribers would not have sufficient experience of assessing clinical/diagnostic competence; meaning they do not meet the eligibility criteria to become DPPs. Respondents recommended that we introduce ‘validation processes for DPPs’ to ensure only appropriate pharmacist independent prescribers become DPPs.

7.52 Participants said there could be a negative impact on trainee pharmacist independent prescribers if they had not been supervised by a doctor or had a doctor involved in their training, as GPs and other pharmacy employers may be less confident in their skills as an independent prescriber.39

7.53 Participants felt that if trainees in the future are more likely to be were supervised by DPPs, there is a risk that doctors would be less likely to sign-up to be supervisors (DMPs), and DMPs may decide to withdraw from supervision, especially given there is no financial incentive.40

**Mitigation**

7.54 As part of accreditation, course providers are required to demonstrate links to their internal policies and standard operating procedures.

7.55 We intend to put in place arrangements to ensure that supervisors have the necessary skills and experience to undertake this role. There will be guidance around DPP requirements, which is being developed by the RPS.

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38 Four consultation respondents.
39 Cardiff stakeholder engagement event, London stakeholder engagement event and Cardiff patient focus group.
40 London stakeholder engagement event and Cardiff patient focus group.
Differences in quality of existing services provided to patients (including data protection)

7.56 We heard a variety of views around ‘quality of service’ to patients. Participants in our engagement events supported the placement of pharmacist independent prescribers across different healthcare settings, as long as it is patient-centred, not target-centred. We heard anecdotal feedback from participants in our patient focus groups that our drive to increase pharmacist independent prescribers could create data protection issues, such as when pharmacist independent prescribers need to access a patient’s history in order to make an accurate diagnosis and be able to prescribe. Participants felt that pharmacist independent prescribers could only be situated in a healthcare setting with a robust and secure IT system. Participants did also feel that having access to patient records was essential for all prescribers.

Mitigation

7.57 If the healthcare setting where the pharmacist independent prescribers is situated has secure and robust IT systems, this would mitigate against data being breached or hacked, ensuring the recent General Data Protection Regulation legislation is complied with. In our standards for registered pharmacies we say “… the pharmacy owner must make sure they comply with all legal requirements including those covering medicines legislation, health and safety, employment, data protection and equalities legislation.”

Feedback from Scotland

7.58 The Scottish Government’s views were that the proposals and our new standards would have a positive effect in Scotland, in that it will strengthen the pool of pharmacist independent prescribers, and using pharmacist independent prescribers to deliver services is a key priority for the Scottish government. They received the new guidance and proposals in a positive light, saying that it should contribute towards Scotland’s ambition for using pharmacist independent prescribers.

Feedback from Wales

7.59 To alleviate the pressure on GP services, NHS Wales will look to the skills of nurses, pharmacists and professions allied to medicine to take up much of the workload associated with the management of people with more stable long-term conditions. It is essential therefore that pharmacists have the necessary skills and abilities to take up extended clinical roles. There will be a greater demand for healthcare professionals to have the ability to prescribe independently if they are to take on the holistic care of this patient group and to ensure that an extended range of common conditions are managed in the community through the community pharmacy network.

Impact of the proposal to extend the supervision of pharmacist prescribers in training to non-medical independent prescribers in practice as well as designated medication practitioners (DMPs)

7.60 In Scotland participants felt that community pharmacists may lack experience to become DPPs.

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41 Glasgow patient focus group and London patient focus group.
42 Meeting with the Chief Pharmaceutical Officer and NES (Edinburgh).
43 NES Conference held in Edinburgh.
8. Welsh Language Scheme

8.1 A Welsh language version of draft standards, the discussion paper and consultation documents was published. This ensured that Welsh speaking stakeholders have the opportunity to provide input. We will also provide a Welsh language version of the finalised standards and guidance.

9. Monitoring

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

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

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

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

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

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

What is the timetable for monitoring, with dates?

9.5 The standards will be kept under continuous review through accreditation, with a substantial review of the standards after 5 years.
Meeting paper

Council meeting on Thursday, 06 December 2018

Public business

Safe and effective pharmacy teams: Assurance for patients and the public about staffing levels in pharmacies

Purpose
To update Council on responses from organisations setting out how they have acted on guidance to ensure a safe and effective pharmacy team and our learning from inspections in respect of sufficient staffing in pharmacies.

Recommendations
The council is asked to:

- Note how organisations have responded to the guidance on safe and effective pharmacy teams
- Note the learning from inspection in relation to staffing levels
- Note the further actions we intend to take

1. Introduction

1.1 In June this year we published guidance setting out what pharmacy owners are expected to do to ensure a safe and effective pharmacy team and meet the standards set out under Principle 2 of the standards for registered pharmacies, including standards related to staffing. We wrote to all pharmacy owners asking them to review the new guidance and take the necessary steps to make sure they are meeting the standards in this area and this has been a key area of focus for our inspections and other regulatory activities. Our inspectors have been
asking for examples and evidence of how the new guidance is being followed and we have continued to require pharmacies to take prompt action when we identify that any standard is not being met. In September, we also wrote to the Company Chemists’ Association, the National Pharmacy Association, the Association of Independent Multiple Pharmacies, Community Pharmacy Scotland and Community Pharmacy Wales asking these organisations to share feedback in relation to any challenges that pharmacies are facing in relation to staffing.

2. The responses from organisations

2.1 We received responses from all five organisations. They have set out actions that some of their members have taken and highlighted the issues they believe are contributing to pressure on pharmacies.

Actions taken following publication of the guidance

- Dedicated staff members to monitor staffing levels and to ensure coverage across pharmacies;
- Employment of more staff where required to obtain the right skill mix;
- Review of staff training and job descriptions to match needs;
- Review of inspection reports to improve quality and safety;
- Reviewing internal policies and guidance;
- Developing field and pharmacy team’s understanding of how staffing models meet our guidance the standards, including reinforcing their understanding of their part in exercising professional judgement about whether it is safe to operate the premises at any given time;
- Reinforcing staff knowledge of the existing support available, including occupational health and use of relief teams for short or long-term absence.

2.2 They have also highlighted some of the difficult decisions taken by pharmacies to ensure they were operating safely at all times, including limiting added-value services such as free home deliveries and compliance aids; putting planned investment in service developments on hold; and limiting evening and weekend opening.

Workforce challenges

2.3 The organisations highlighted some wider challenges which affected staffing levels in community pharmacies, including:
• the impact of funding cuts in England;
• difficulty in recruiting Accuracy Checking Technicians;
• declining pipeline in newly qualified pharmacists;
• the impact of Brexit on the recruitment of pharmacy staff from within the EEA; and
• further segmentation of the pharmacy sector with new roles for pharmacists across the healthcare sector.

2.4 Comments were also received about the nature of questions asked by inspectors with some viewing these as disproportionate and intrusive and not always taking account of the individual nature of each business.

3. Our findings from inspection

3.1 Standard 2.1, which relates to the adequacy of staffing, has appeared in the top five standards not met throughout 2018, although the overall number – 28-29 pharmacies each quarter remains low and equates to around 3% of the pharmacies inspected. It represents an increase on the numbers identified in 2016 and 2017 (which ranged from 11-20 each quarter).

3.2 The guidance we issued provided inspectors with a framework which enables them to consider a broader evidence base when assessing whether there are sufficient staff within a pharmacy. Where inspectors have found the standard to be not met, the evidence has consisted of: longer waiting times for patients, dispensing backlogs, delays in date and fridge temperature checks; no staff meetings or development appraisals; staff working after hours. Typically, this will indicate a pharmacy is failing several standards, where there is difficulty in recruiting and a lack of contingency planning for absences. There are also pharmacies where the reason for the standard being failed is due to staff having not been enrolled on a training course or where there has been a delay in recruiting additional staff.

Taking action where staffing levels are insufficient

3.3 Where a pharmacy has not met the standard, we require the pharmacy owner to complete an improvement action plan. In relation to the standard on sufficient staffing, pharmacies have typically made the necessary improvements by employing more staff, sometimes using staff from other branches; better deployment of available staff such as training counter staff to work in the dispensary, reducing the services offered or moving services to other branches.
4. Next steps

4.1 While there have been several actions taken following publication of our guidance, we have an ongoing need to understand the impact of the guidance and the continuing challenges reported through a number of channels, including the pharmacy trade bodies. As a result, there are three actions we intend to take:

i) We will bring together trade and professional bodies in the New Year to identify further actions that can be taken by all relevant organisations to provide further assurance for patients and members of the public in respect of staffing levels. We will highlight learning from our inspections; re-emphasise the expectations set out in our guidance; seek further assurances about how pharmacy owners are determining appropriate staffing levels and clarify the roles that regulatory, professional and trade organisations need to play.

ii) We will continue to assess whether pharmacies are meeting the required standard through our inspections. Subject to Council approval of our approach to registered pharmacies, we will ensure that our inspectors are seeing pharmacies exactly as patients and the public do, with no previous announcement that an inspection is imminent. In due course, and subject to Council decisions in light of the consultation on registered pharmacies, publication of inspection findings has significant potential to strengthen transparency and accountability in relation to safe staffing as with other aspects of the standards.

iii) We will consider a possible thematic inspection of staffing levels as part of our planning for 2019/20, subject to approval by Council of our approach to inspecting registered pharmacies. Thematic inspections provide an opportunity to scrutinise the issue in more depth than is possible during a routine ‘snapshot’ inspection.

5. Equality and diversity implications

5.1 As part of the further work identified above, we will consider whether there are any particular equality and diversity issues arising in the implementation of our guidance, taking account of the different context and size of pharmacies.

6. Communications

6.1 Nothing in addition to the points set out in paragraph 4.1 above.
7. Resource implications

7.1 There are no additional resource implications beyond what we are already budgeting for as part of our plans.

8. Risk implications/Monitoring and review

8.1 We will continue to monitor how pharmacies are meeting the standards through our inspections and continue our engagement with pharmacy owners to ensure the guidance is being followed.

Recommendations

The council is asked to:

- Note how organisations have responded to the guidance on safe and effective pharmacy teams
- Note the learning from inspection in relation to staffing levels
- Note the further actions we intend to take

Mark Voce, Director of Education and Standards
General Pharmaceutical Council

mark.voce@pharmacyregulation.org

29 November 2018
Meeting paper

Council on Thursday, 06 December 2018

Public business

Developing our approach to regulating registered pharmacies

Purpose
To provide Council with a report on the proposed principles which underpin our updated approach to regulating registered pharmacies, and the operational implications of them. The developments will ensure we can continue to effectively provide assurance on, and drive continuous improvement in, the quality of pharmacy services for patients and the public.

Recommendations
1. Council is asked to approve the following principles which underpin our updated approach to regulating registered pharmacies. These principles were all referenced within the consultation document.
   a. To be flexible, agile and responsive to the information we hold, intelligence we receive and issues we identify within pharmacy.
   b. Inspections should reflect as closely as possible how patients and the public experience pharmacy services day to day.
   c. The overall outcome of an inspection is clear and understandable to members of the public and enables pharmacy owners to be held to account against the standards.
   d. All standards for registered pharmacies need to be met every day.
   e. That the outcome of an inspection is open, transparent and accessible to members of the public (including where improvement action or regulatory enforcement action is required as a result).
   f. That insights from inspection activities are accessible to everyone in the pharmacy sector.

2. In doing so, Council is asked to note the operational implications of the principles underpinning our updated approach, set out in Appendix 1.

3. Council is also asked to note the initial draft of our proposed enforcement policy for registered pharmacies, set out in Appendix 2.
4. In addition, Council is asked to note, that if approved the intention is to:
   a. Start publishing inspection reports in quarter one of 2019/20.
   b. Undertake an evaluation of the effectiveness of the changes to our approach in 2021.

5. Council is asked to note that the proposed principles represent a development in aspects of the model that is already operating. These proposed changes have been informed by the outcomes of the consultation and the equalities and regulatory impact assessments presented at the November Council meeting. They have also been informed by the independent evaluation of our current approach, undertaken in 2015.

6. If Council is minded to approve the changes in principles, we will use an operational reference group of representatives from pharmacy to help inform any final refinements to their practical implementation. This group is in the process of being set up.

1. **Introduction**

   **Background to our approach to regulating registered pharmacies**

1.1. The approval of outcome-focused standards for registered pharmacies by Council in September 2012 signaled the start of our modernisation of the regulation of registered pharmacies. In November 2013, our inspection model changed to support the modernised approach, the core principles of which ensured regulation could play a dual role in providing both assurance and improvement. Assurance to patients and the pharmacy sector that registered pharmacies are meeting standards, whilst also acting as a catalyst for driving improvement in the quality of pharmacy services and care for the public.

1.2. Two other core principles which remain fundamental to our approach to regulation today include an important commitment that our approach should be an enabler to responsible innovation, as well as to meeting the principles of right touch regulation. The latter of these is embedded in the operating principles in our strategic plan. These remain unchanged as part of these proposals.

1.3. In February 2015, we published an update paper, Modernising pharmacy regulation: from prototype to implementation. This highlighted the important progress that had been made as well as areas we were planning to adapt and change our approach in the future, including changes to how inspections were rated.

1.4. An independent evaluation of our modernised approach to regulating registered pharmacies was commissioned to understand how well it was working. Overall the evaluation found that our approach was working well, with a few areas highlighted for us to consider. Areas highlighted were predominantly around ambiguity between the different ratings used and the terminology of some of the labels, such as ‘satisfactory’. The report, published in August 2015 is available on our website. This helps to provide a useful context for why we are not proposing a whole scale change in our approach.

1.5. In May 2018 new powers to regulate registered pharmacies came into effect, including to publish inspection reports and enforcement powers. With regards to the former, this fulfils a long-standing intention of Council to do so.

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1 **Evaluating the GPhC's approach to regulating community pharmacies**
1.6. As a result, from May to August 2018 this year we consulted on proposals for developing our approach to regulating registered pharmacies further. Council received the feedback from this, along with the equalities and regulatory impact assessments, at the November Council meeting.

1.7. Finally, in considering the proposed principles and the operational implications of them, it is important to be mindful that the elements of the existing model do not exist or operate in isolation. They should be viewed as a set of interlinking proposals which together form part of a whole approach to our regulation of registered pharmacies. Furthermore, the principles represent only some aspects of the overall approach itself. The model itself remains largely the same as is operating now.

1.8. The rest of the report seeks to provide a summary of the proposed principles which underpin our updated approach to regulating registered pharmacies, signposting the operational implications of them to inform Council’s decision making. It does not set out to rehearse the content of the feedback report from the consultation, as these have already been set out in full to Council, nor does it cover elements of our approach which were not consulted on, remain unchanged and will continue to operate as they do now. Appendix 1 sets out in more detail the operational implications of the proposed principles.

2. Proposed changes to principles underpinning our approach

Flexible, agile and responsive to the information we hold, intelligence we receive and issues we identify

2.1 How pharmacy services are delivered is changing at pace. With the introduction of new service models of delivery and a greater use of technology, our approach to regulating registered pharmacies can’t stand still if we are to remain effective and relevant.

2.2 To deliver a more flexible, agile and responsive approach to the way we regulate registered pharmacies, we propose to introduce three new types of inspection. These will be routine, intelligence led and themed inspections. This will enable us to use our inspection resource more flexibly using the most appropriate type of inspection based on the context, intelligence and issues we hold or receive about pharmacies. This will enable us to provide assurance and drive continuous improvement at an individual pharmacy level, as well as sector wide in a more tailored way.

2.3 Whilst the majority of respondents to the consultation supported this approach, we are proposing a few additional operational measures to support this development in principle, because of some of the feedback received. These are set out in more detail in Appendix 1. Council is asked to note that we intend to use the operational reference group to test out and refine these additional measures.

Reflect as closely as possible how patients and the public experience pharmacy services day to day

2.4 Our inspections should reflect as closely as possible the quality of services patients and the public experience. This will provide additional assurance that the outcome of an inspection more accurately reflects how well a pharmacy is meeting our regulatory standards day to day.

2.5 To deliver on this principle, we propose to move to unannounced inspections as a general rule. This was strongly supported by members of the public and the majority of respondents to the consultation also supported this proposal. A common theme from those that provided feedback was that this had the potential to uncover poor practices, such as low staffing levels which may present a patient safety risk.
2.6 In proposing this we recognise that there will be exceptions to the rule. For example, closed pharmacies within prisons, or other secure environments such as airports, where access may be restricted for good reasons. We will ensure that information is available on our website about the circumstances in which unannounced inspections may not be possible or appropriate.

2.7 As a result of some comments made by respondents to the consultation on the potential impact of an unannounced inspection on patient safety, Appendix 1 sets out some additional actions we will take as a result.

The overall outcome of an inspection is clear and understandable to members of the public and enables pharmacy owners to be held to account against the standards.

2.8 As an independent regulator for the public it is important that those using pharmacy services are clear whether our standards have been met or not. With the power to publish the outcome of an inspection now in effect, this becomes even more important

2.9 It is also important to pharmacy owners and the pharmacy team that the outcome of an inspection is clear and has limited scope for misinterpretation. This will ensure efforts are focused on meeting and improving standards.

2.10 To deliver this principle we propose that the overall outcome of an inspection changes to a simpler binary judgement, setting out whether all standards have been met or not. This provides a clean and clear assessment on whether our standards are met - our core assurance role. It also promotes accountability and removes any opportunities for ambiguity, addressing one of the concerns raised within the independent evaluation.

2.11 The majority of respondents to the consultation supported this proposal and importantly a large majority of members of the public responding to the YouGov² survey thought it would make it clear to understand. Given we are a regulator for the public, it is key that the outcome of an inspection meets their needs.

2.12 The proposal is further supported by the intention to use four possible findings at principle level of the standards for registered pharmacies. Combined with the overall binary outcomes this provides the granularity in performance against our standards that will enable us to identify poor, good and excellent practice. In doing so we retain the ability to be able to drive continuous improvement in pharmacy services and share the learning and insights with the sector more regularly.

2.13 Having reflected on the range of comments made in this area, what is clear is that whilst the majority of respondents supported this proposal, this aspect of our approach will always attract a range of opinions, just as our current four graded rating system has. Given that context, we have taken the view that as a regulator for the public, it is important that the outcome of an inspection works for the public first and foremost.

2.14 The simpler binary judgement meets our core assurance role and supported by the four possible findings at principle level ensures we can also meet the second core element of our approach to ensure regulation drives continuous improvement, enabling owners and their teams to measure their performance. The

² All figures, unless otherwise stated, are from YouGov plc. Total sample size was 2040 adults. Fieldwork was undertaken between 8th- 9th August 2018. The survey was carried out online. The figures have been weighted and are representative of all GB adults (18+).
combination of these we believe goes some way to addressing some of the comments provided as part of the feedback.

2.15 Appendix 1 sets out some of the additional operational measures we will take as a result of feedback received.

All standards for registered pharmacies need to be met every day

2.16 Pharmacies should already be meeting the standards for registered pharmacies every day. These standards have been in place since September 2012. Pharmacy owners also sign an annual declaration at renewal to say that they are meeting the standards for registered pharmacies.

2.17 To deliver this principle we propose that our approach to regulation and inspection should reflect that a pharmacy must be meeting all standards every day to meet our standards overall. This principle is also inextricably linked and goes hand in hand with the preceding principle in moving to a simpler, clear and unambiguous binary judgment outcome following an inspection. This is because by definition, standards are either met or not met.

2.18 The follow-on actions for a pharmacy not meeting our standards will remain the same as they are now. Any pharmacy not meeting a standard is required to produce an improvement action plan setting out how they will improve and by when. Progress is monitored by the inspectorate and then re-inspected. As recognised by the independent evaluation, improvement action plans have proved to be a very successful mechanism for securing necessary improvements in standards. For those pharmacies that do not make the necessary improvements, we now have strengthened enforcement powers to ensure that they do.

2.19 Council will be aware from the consultation report that our proposal that pharmacies must meet all of the standards to meet standards overall divided opinion. While significantly more respondents to the YouGov survey supported than opposed this proposal, the majority of those responding to the consultation survey did not. Whilst we acknowledge some of the common themes of comments that it was unfair, and should depend upon the nature of the unmet standard and its potential impact on patient safety, we remain of the view that the standards for registered pharmacies have been in place now since 2012. When we first started inspecting, the standards were very new to pharmacy and inspection played an important part in raising understanding and awareness of the outcome focussed standards and their implementation. Six years on it is important that our regulation reinforces the need for standards to be met every day. Whilst the majority of the sector did not agree with this proposal, there were many respondents, however, that also thought standards should be met by all pharmacies at all times and that this was the right thing to do.

2.20 Having reflected on the comments made we will undertake some additional operational actions to address some of these areas. This will include producing clear information and operational guidance on what constitutes a minor non-compliance. Appendix 1 sets these out in more detail.

Outcome of an inspection is open, transparent and accessible to members of the public

2.21 With the power to publish inspection reports, we are now able to address a long-standing intention of the Council to publish the outcome of an inspection. As a regulator for the public it is important that the outcomes of inspections are accessible to them to help provide assurance and empower and inform their decision making. For the pharmacy sector as a whole, publication will allow them to use the information in the reports to improve. It is also important that we should be open and transparent about not only the
outcome of an inspection, but also the evidence we have gathered to come to that decision. Publication will also bring us into line with the practice of the majority of other regulators.

2.22 There are three aspects to this proposal. The publication of inspection reports; the publication of any improvement action plans or enforcement action, and the display of the outcome of an inspection in the pharmacy.

2.23 To deliver the first aspect of this principle, we are proposing to publish a summary report on our website with a link to a more detailed report. Users will be able to interact with the information, enabling them to search for pharmacies in different ways, and view the information they want to in a way to best meet their needs. This approach meets with what we heard from patients and the public engagement groups held as part of the development process. The majority of respondents to the consultation supported the publication of inspection reports, and there was overwhelming support among members of the public responding to the YouGov survey. Council should also be aware that inspection reports will also be published alongside the pharmacy’s entry on the online register.

2.24 To deliver the second aspect of this principle, we also intend to publish any improvement action plans or details of enforcement action which follow on from an inspection. This is because improvement action plans or enforcement actions are part of the inspection process, and our commitment to transparency should not be selective. Importantly, it was clear from the patient and public involvement groups that they would find it reassuring to know that improvement action was being taken, that they could see the content of it if they so wished, and that the regulator was monitoring progress. This was also reinforced by a large majority of members of the public who responded to the YouGov survey who were clearly in favour of publication. Importantly, they were significantly more likely to visit a pharmacy on the basis of knowing that that improvement actions were underway.

2.25 Council will be aware from the consultation report that those who responded to the consultation on the publication of improvement action plans were equally split for and against this aspect. However, we believe paragraph 2.24 importantly addresses a number of the comments made with regards to public confidence in relation to using a pharmacy with an improvement action plan in place. In addition, we intend to work with the operational reference group on fine-tuning how much of an improvement action plan should be published. We agree with comments made that this should avoid the inclusion of any personal identifiable or sensitive information. We will also work with the group to refine what we regard as commercially sensitive information that should be excluded from a published report for good reasons.

2.26 To deliver the third aspect of this principle, we are proposing to encourage pharmacies to display the outcome of an inspection in the pharmacy. Council will be aware that we do not have the power to require or enforce the display of an inspection outcome. This is the same position for the majority of other regulators. However, in the meantime, to try and ensure there is some consistency for members of the public and for the avoidance of any confusion, we will provide a simple GPhC branded sign which pharmacies can use on a voluntary basis, following an inspection.

2.27 Council will be aware from the consultation report that respondents were equally split in their views on whether pharmacy owners should be expected to display their inspection outcomes in the pharmacy. YouGov survey respondents supported this proposal by a vast majority. Generally, throughout our approach to the changes in principles we have tended to put the public’s needs first where there is a difference in opinion. Our proposal to encourage pharmacies to display the outcome of an inspection follows that logic.
2.28 Appendix 1 sets out additional operational actions we are taking as a result of comments made as part of the consultation. This includes the exploration of other more potentially holistic approaches to connect members of the public in all pharmacies with the regulator and information about the pharmacy and the standards they should expect.

**Insights from inspection activities are accessible to everyone in the pharmacy sector**

2.29 This proposed principle builds on our approach to support and drive continuous improvement in the quality of pharmacy services and care further, and not just when a pharmacy receives an inspection. Linked with the proposed four possible findings at principle level earlier, we want to ensure notable practice identified within inspection reports can be shared easily with the sector to maximise its potential value. We will create case studies which others can learn from. To ensure these are easily accessible, they will be sit within an online knowledge hub, which will be searchable and interactive on a self-service basis.

2.30 We received strong support for this proposal. We are also aware that to be successful, the information contained within the case studies needs to be helpful to those reading them. We will be refining the length, content and tone of these using the input from the operational reference group before they go live.

3. **Draft enforcement policy for registered pharmacies**

3.1 The effective use of our enforcement powers\(^3\) in regulation is important to secure compliance with our standards for registered pharmacies and, where necessary, to ensure that pharmacy owners who have not complied may be held to account. As part of our earlier consultation, we outlined the principles that guide our approach to enforcement and gave a commitment to publish an enforcement policy.

3.2 Council is asked to note the initial draft of our enforcement policy for registered pharmacies (Appendix 2) and to provide any feedback and comment. The policy is intended to do the following:

- set out the principles and approach we will follow when using our enforcement powers;
- summarise the range of enforcement options available to us;
- outline the criteria we will take into account when making decisions about which enforcement options to use;
- support consistent decision-making about when to use our enforcement powers; and
- align with our wider strategic approach to regulation.

3.3 Following feedback and comments from Council, we will take into account any feedback from Council and refine the policy in preparation for publication in due course. As Council will note from the policy, we have highlighted a number of areas on which we will be developing more detailed information, including the publication and disclosure of enforcement action, as well as more detailed information about the use of our powers under the Regulation of Investigatory Powers Act 2000. We will also consider how these sit

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\(^3\) The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (Commencement) (England, Wales and Scotland) Order of Council 2018 commenced on 24 May 2018 all the provisions of the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016, which relate to the law of England, Wales and Scotland but were not yet in force.
alongside our overall approach to regulation more widely, and in conjunction with existing fitness to practise and prosecution policies.

4. Equality and diversity implications

4.1 Council has previously considered a full equality impact assessment consistent with our responsibilities as set out in the Equalities Act 2010, as part of the consultation report at the November Council meeting.

4.2 The new website we are developing, on which we will publish inspection reports and share case studies through the knowledge hub, will meet WCAG 2.0 accessibility guidelines and will feature Welsh translation of inspection reports, so it is accessible for all audiences.

5. Communications

5.1 We will communicate the Council’s decisions on how we will develop our approach to regulating registered pharmacies to all key stakeholders, including respondents to the consultation, through a range of channels including tailored emails, a press release, our social media channels and meetings with our key stakeholders.

5.2 A communications plan is being produced which will set out the communications activities for the implementation of the new approach. This will include producing engaging and interactive resources for pharmacy professionals, pharmacy owners and members of the public, so they can quickly understand and engage with our new approach.

5.3 Work is already underway to develop the new website for the publication of inspection reports, and a key focus in the next period will be in making sure through testing that the new website is accessible and easy to use for all audiences, including registrants and members of the public.

6. Resource implications

6.1 The ongoing operational resource implications for the changes to how we regulate registered pharmacies, including publication of inspection reports and notable practice examples, have been accounted for in existing budgets. One off costs contained within existing budgets relate to the design and build of a publication website and knowledge hub and adaptations to supporting operational inspection infrastructure.

7. Risk implications

7.1 The principles underpinning our approach set out in this paper are linked. If Council is not minded to approve all or some of them, this could undermine the overall approach and could require us to look at the model again. This could lead to a delay in the publication of inspection reports. With the power to publish which came into force in May 2018, there is a risk that this could present an unacceptable delay.

8. Monitoring and review
8.1 We have signalled our intention to undertake a full evaluation of the changes to our approach in 2021. We will also be updating the existing feedback mechanisms from pharmacies and owners already built into our approach. This will provide us with some real time and ongoing feedback about the changes.

**Recommendations**

1 Council is asked to approve the following principles which underpin our updated approach to regulating registered pharmacies.

   a. To be flexible, agile and responsive to the information we hold, intelligence we receive and issues we identify within pharmacy.

   b. Inspections should reflect as closely as possible how patients and the public experience pharmacy services day to day.

   c. The overall outcome of an inspection is clear and understandable to members of the public and enables pharmacy owners to be held to account against the standards.

   d. All standards for registered pharmacies need to be met every day.

   e. That the outcome of an inspection is open, transparent and accessible to members of the public (including where improvement or regulatory enforcement action is required as a result).

   f. That insights from inspection activities are accessible to everyone in the pharmacy sector.

2 In doing so, Council is asked to the note the operational implications of the proposed principles underpinning our updated approach, set out in Appendix 1.

3 Council is also asked to note the initial draft of our proposed enforcement policy for registered pharmacies, set out in Appendix 2.

4 In addition, Council is asked to note, that if approved the intention is to:

   a. Start publishing inspection reports in quarter one of 2019/20.

   b. Undertake an evaluation of the effectiveness of the changes to our approach in 2021.

5 Council is asked to note that the proposed principles represent a development of aspects of the model that is already operating. These have been informed by the outcomes of the consultation and the equalities and regulatory impact assessments presented at the November Council meeting. They have also been informed by the independent evaluation of our approach undertaken in 2015.

6 If Council is minded to approve the proposed principles, we will use an operational reference group to help inform any final refinements to their practical implementation. This group is in the process of being set up.
Claire Bryce-Smith, Director of Insight, Intelligence and Inspection
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3 December 2018
## Proposed principles

To be flexible, agile and responsive to the information we hold, intelligence we receive and issues we identify within pharmacy.

- We will introduce three types of inspections:
  - routine
  - intelligence-led
  - themed
- Our routine inspection programme will provide assurance that standards for registered pharmacies continue to be met. This will be increasingly informed by indicators of risk for programming when a pharmacy should be inspected.
- Intelligence-led inspections will be used to act rapidly on information, intelligence or concerns received about the quality or safety of pharmacy services as appropriate.
- Themed inspections will be used to identify learning and good practice on specific issues and themes in more depth that can be shared across pharmacy. These will involve a number of pharmacies.

## Operational implications

Inspections should reflect as closely as possible how patients and the public experience pharmacy services day to day.

- We will move to unannounced inspections as a general rule.
- There will be exceptions to that general rule including for example where pharmacies are within closed or secure environments which require access to be pre-arranged.

The overall outcome of an inspection is clear and understandable to members of the public and enables pharmacy owners to be held accountable.

- We will use a simple binary judgement as the overall outcome of an inspection, supported by four possible findings at a principle level.
  - Pharmacies will receive an overall outcome of either standards met or standards not all met.

## Additional actions to be taken post consultation feedback

1. We will produce further explanatory information on our website as to when we will use the different types of inspection to allay any concerns about additional burdens or lack of clarity.
2. We will update our website content with information that clearly explains how we will use indicators of risk in programming pharmacies for routine inspections.
3. We will ensure that pharmacies are clear what type of inspection is being undertaken at the start of every inspection.
4. We will produce information about the operational principles we will use to triage incoming information, intelligence and concerns to help us make decisions as to when to act or not. This will help to clarify comments made about the risks of vindictive reporting.
5. We will work with the operational reference group to test out whether the information referenced above is clear and helpful.

Appendix 1
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<th>Proposed principles</th>
<th>Operational implications</th>
<th>Additional actions to be taken post consultation feedback</th>
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| to account against the standards. | o The four possible findings at principle level will be standards not all met, standards met, good practice and excellent practice.  
• The only occasion we will not use an overall binary outcome will be for themed inspections. These will be primarily focusing on very specific themes or issues across a number of pharmacies, the primary purpose of which being to learn from practice. | of our engagement with patients and the public groups and from respondents to the consultation.  
a. This will help to inform members of the public of the standards they should be expecting to receive when visiting a pharmacy.  
2. We will also produce articles in Regulate, on our website and jointly with representative bodies where possible about our rationale for simplifying and moving away from ratings model to promote understanding of how the overall outcome provides assurance and the findings support, promote and help to drive continuous improvement.  
3. The follow-on process for standards not all met and timescales for meeting standards will be available on the new reporting website and clearly signposted on the inspection reports. Please see principle below for more detail.  
4. We will work with the operational reference group to ensure that the information and definitions are clear.  
| All standards for registered pharmacies need to be met every day. | • We will require all standards to be met to receive a standards met outcome.  
• Any standard not met will require an improvement action plan (as is the case now), setting out what action will be taken to improve and by when.  
• In some circumstances we may also take formal enforcement action at the start, in line with our enforcement policy.  
• Progress on improvements underway will be monitored by the inspectorate.  
• A reinspection will occur at 6 months giving enough time for improvements to be made and importantly sustained. If the pharmacy meets all standards a new report will be published.  
• Failure to meet the standards at this point in most circumstances will trigger formal enforcement action. | 1. We will update our decision-making framework to reflect the change to the overall outcome of an inspection. This is the framework inspectors use to help make decisions and will be available on the website, ensuring we are open and transparent about how we make decisions.  
a. This provides examples of outcomes for each standard.  
2. We will provide additional information outside of the decision-making framework on examples of what constitutes a minor non-compliance that would not result in a standard not being met for each standard.  
3. We will provide additional information on the website of the follow-on action for a ‘standards not all met’ outcome, including a simple flowchart. This will include clear expected timelines for meeting standards and re-inspection.  
4. We will publish our enforcement policy so that the profession and members of the public are clear on when we may use these powers and the process we will follow.  
5. We will work with the operational reference group to check that the operational information provided is helpful and clear. |
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| That the outcome of an inspection is open, transparent and accessible to members of the public (including where improvement or regulatory enforcement action is required as a result). | • We will publish a summary report of all inspections with a link to the detailed inspection report on an easily searchable website as well as on online register.  
  o The summary report will contain a short narrative explaining the key judgements made under each of the five principles of the standards for registered pharmacies, written in plain English.  
  o The detailed report will contain the same judgements that are in the summary report along with the supporting evidence for them.  
• The inspection report will also be published alongside the pharmacy’s entry on the online register.  
• Alongside the summary report we will publish the improvement action plan, and or details of any formal enforcement action taken where this has been actioned.  
• Any new inspection will replace the previous inspection report, which will be available in a section showing previous inspection history.  
• All previous inspection reports will remain published in line with the relevant timelines of our publications and disclosure policy when approved.  
• We will encourage all pharmacies to display the outcome of an inspection in a pharmacy.  
  o We will provide pharmacies that have been inspected with a GPhC branded sign for display. | 1. We are working on the development of an interactive website for the publication of inspection reports. This will be subject to user testing to ensure a positive customer experience.  
2. We will produce clear information on the process of publication, including the factual checking of the accuracy of the inspection report stage with owners of pharmacies, (which happens now), as well as an additional review of a scored judgement stage before publication. This will provide a route for owners to ask for the outcome of an inspection to be reviewed where they disagree that the outcome reflects our decision-making framework before publication.  
6. We will pilot the review of a scored judgement process as well as commission independent testing before publication starts.  
7. We will work with the operational reference group before publication to help inform what aspects of the improvement action plan are not suitable for publication – because of sensitive commercial or personal identifiable information.  
8. We will provide pharmacies with a GPhC branded outcome sign for displaying in their pharmacy.  
9. We will consider making the display of inspection outcomes a requirement as part of the review of standards for registered pharmacies in absence of legal powers to enforce  
10. We will explore the use of technology to connect the public at a pharmacy with the GPhC website at all times. For example, exploring the provision of branded unique QR codes for all pharmacies at registration for display. |
DRAFT

Registered pharmacies enforcement policy

Effective from XXXX 2018

1. Introduction and purpose

1.1 We have an important role in providing assurance to people that the pharmacy services they and their families use will be safe and effective. We also want to drive continuous improvement in the quality of care that people receive when using pharmacy services.

1.2 We have a range of enforcement options that we use to achieve these objectives, including statutory enforcement powers. The effective use of our enforcement powers in regulation is important to secure compliance with our standards for registered pharmacies and, where necessary, to ensure that pharmacy owners who have not complied may be held to account. This policy:

- sets out the principles and approach we will follow when using our enforcement powers
- summarises the range of enforcement options available to us
- outlines the criteria we will take into account when making decisions about which enforcement options to use
- supports consistent decision-making about when to use our enforcement powers, and
- aligns with our wider strategic approach to regulation

1.3 We have published this policy to ensure that the principles that underpin our approach to enforcement are clear. Our inspectors and others tasked with making decisions in individual cases are required to follow this policy.

1.4 This enforcement policy cannot substitute for judgement in individual cases. There will be occasions when, depending on the facts of an individual case, it will not be appropriate to follow the exact steps described in this policy. It should be read as a general guide to good practice when carrying out or considering enforcement action.

1.5 Decisions about these matters, and whether to proceed to the next state of enforcement action, should be based on the information available to us at that time.

1.6 This policy focuses on registered pharmacies and enforcement action may be against the pharmacy owners. In some cases, we may identify concerns or issues about individual pharmacy professionals that require further investigation through our fitness to practise processes. These will be considered in line with our published guidance and procedures.
1.7 We accept that there will be occasions when more facts emerge later in the process, or disputes of fact are resolved, and therefore enforcement action is no longer required. If we believe such a stage has been reached, we will cease enforcement, where appropriate.

2. **Our approach to enforcement**

2.1 Our overall approach is to support and encourage pharmacy owners to meet the standards for registered pharmacies. We are committed to using the minimum regulatory intervention required to achieve the desired result, known as 'right-touch' regulation.\(^1\)

2.2 Where possible we will try to secure the safe and effective practice of pharmacy at or from a registered pharmacy through open communication and dialogue with the pharmacy owner.

2.3 We take statutory enforcement action in situations when a pharmacy owner does not complete an improvement action plan and carry out the necessary changes to make sure our standards are met, or in situations when there is a serious risk to patient safety. We define statutory enforcement action as any use by the GPhC of the range of statutory enforcement powers set out in the Pharmacy Order 2010 and the Medicines Act 1968.

2.4 We make decisions about when to use our enforcement powers consistently and proportionately, so that we take only the steps we need to take to make sure a pharmacy meets the standards and to safeguard patients and the public. We will act swiftly, robustly and fairly, with a clear focus on patient safety.

2.5 Where another regulator or organisation is better placed to manage the concerns, we will work collaboratively with that organisation. If the GPhC is not the appropriate enforcement authority we will notify the relevant organisation and assist them where appropriate and necessary.

2.6 We also make full use of all intelligence and data that we collect in order to fully support and inform our decision-making. This includes information gathered through our inspections; from our work with other regulators; from concerns raised by individuals or organisations; and, from the wider public. Making full use of our intelligence enables us to focus our efforts on proactively anticipating and responding to issues, and tailoring our regulatory responses to achieve the desired results in the best and quickest way.

3. **Key principles that guide our use of enforcement**

3.1 We use our enforcement powers to meet our statutory objective of protecting, promoting and maintaining the health, safety and well-being of patients and the public, including people who use pharmacy services. The following principles guide our decision-making:

**Proportionality**

3.3 Proportionality is about responding appropriately and taking the right action to secure compliance. This will generally involve taking account of the degree of the risk of harm caused by non-compliance. Sometimes, however, we will need to take enforcement action even though the risks may be uncertain.

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• we take action that we consider to be proportionate. This means that our response, including the use of enforcement powers, must be assessed by us to be proportionate in the circumstances of an individual case.

• where appropriate, if the pharmacy owner is able to improve the service on their own and the risks to people who use services are not immediate, we will generally work with them to meet our standards rather than taking enforcement action.

• we take enforcement action people are at an unacceptable risk of harm or registered pharmacies are repeatedly or seriously failing to meet our standards.

Consistency

3.4 Consistency means taking a similar approach in similar cases to achieve similar outcomes within which a degree of discretion is available. We aim to be consistent in applying our enforcement powers by, as far as possible, dealing with similar cases in a similar manner. However, it important to note that:

• consistency does not mean that we use the same enforcement option every time our standards are not met.

• the facts in one case are rarely replicated exactly in another case. Even though we aim to achieve broad consistency, we will take different decisions in cases where the facts are not the same.

• decisions about specific enforcement action rely on individual professional judgement and each case is evaluated on its own facts and circumstances and the assessed risks.

• we train and support our inspectors and others involved in the decision-making processes to promote consistency in our approach and we have a range of oversight and quality assurance processes.

• we collaborate with other regulators where appropriate, to promote consistent approaches.

Transparency

3.4 Transparency is about helping pharmacy owners to understand what is required of them at the outset and setting out what they may expect from us in return. It also involves making clear what remedial action is required and providing details of any rights of appeal.

• we are open and transparent about our approach to enforcement, consistent with how we carry out our regulatory functions.

• we are clear about what we expect and how we approach cases where registered pharmacies are not meeting our standards.

• we publish relevant information including the factors that we take into account when making decisions and the processes for appeals and making representations against our decisions.

• we also publish information about the enforcement action we have taken, when this is appropriate and allowed by law.

[Note: our publication and disclosure policy will be updated in due course to reflect how we publish information about enforcement action]

• we share learnings from or enforcement activity wherever possible so that it can be used by pharmacy owners and the sector more widely.
Targeting

3.5 Targeting of enforcement action means prioritising and directing our regulatory efforts effectively. We use strategic and operational risk assessment to focus our resources where we believe they are most needed.

- we concentrate on the activities which create the most serious risk, either because the nature of the activity is inherently high-risk or because of a lack of appropriate controls or appropriate response in other less high-risk activities.
- this involves identifying and focusing on those responsible for the risk.

Accountability

3.6 Our enforcement activities will be open to public scrutiny, with clear and accessible policies, and fair and efficient complaints procedures.

- we are accountable to the public and our enforcement actions can be judged against the principles and approach set out in this policy.
- pharmacy owners need to know what to expect when our inspectors visit and how to raise any complaints they may have.

3.7 These principles apply to both the enforcement of individual cases and the management of our enforcement activities as a whole. They are not applied in isolation and are informed by an understanding of the sector and the environment in which registered pharmacies are operating.

4. Enforcement options

4.1 We have a range of enforcement options available to us to secure compliance. These can be used at any stage and are not sequential. In some cases, we may decide to use a combination of enforcement options.

4.2 We use these enforcement options flexibly, depending on the nature of the non-compliance and the desired outcome of the intervention. In deciding what level of enforcement action is appropriate, our inspectors exercise discretion and professional judgement according to the circumstances found.

4.3 Our inspectors are guided in this process by this policy, which provides a framework for consistent enforcement decision-making and takes account of the pharmacy context on a case by case basis.

4.4 We seek resolution by choosing the most appropriate enforcement option in individual cases, which may involve using one or more of the following options set out below.

The range of enforcement options available to us

4.5. We have a wide range of enforcement options available to us from improvement action plans through to statutory enforcement powers such as improvement notices and conditions. We have set out more information about our range of powers below.

- Improvement action plans
  Generally, we use improvement action plans as our first response to failures to meet our standards for registered pharmacies.
If one or more standards are not being met, and there is no immediate risk to the public or patients, we will require pharmacy owners to develop an improvement action plan, setting out what they will do, within a set time, to put right the issues and meet the standards.

We follow up with these pharmacies to make sure they make the improvements needed and that the standards are fully met.

The use of an improvement action plan does not prevent further statutory enforcement action being taken in some cases where this is necessary. However, improvement action plans enable pharmacy owners to engage constructively with us about how to meet the standards and limit the impact of any non-compliance.

Where an action plan is not completed within the time given, or the pharmacy owner has made no attempt to comply with the action plan after repeated reminders, we consider other enforcement options.

- **Conditions**

Registered pharmacies can have conditions attached to their registration. We have legal powers to impose conditions on specific pharmacy premises when this is necessary for the purpose of securing the safe and effective practice of pharmacy at those premises. We have powers to impose conditions on making the premises entry or subsequently (whether on renewal of the entry or otherwise).

Imposing, varying or revoking conditions of registration is a flexible enforcement process that we can use in a variety of different ways to ensure that pharmacy owners are meeting the standards and providing safe and effective care. We use conditions flexibly and in appropriate situations. They may be used to restrict risky or unsafe activities or practices.

We give pharmacy owners reasonable notice in writing of the condition to be imposed or, as the case may be, of the variation or revocation of an existing condition and of the date from which that condition, variation or revocation is to have effect. However, we also have legal powers to impose, vary or revoke conditions, with immediate effect, if we consider that giving reasonable notice would prejudice the health, safety and well-being of members of the public. In such cases, we still notify the pharmacy owner in writing. Pharmacy owners may also apply for any of the conditions imposed to be varied or revoked.

A failure to comply with conditions relating to the standards can lead to an improvement notice being issued (see below for more information).

- **Improvement notices**

We also have legal powers to serve an improvement notice when our inspectors have reasonable grounds for believing there is a failure to meet the standards, or a failure to meet conditions relating to the standards.

We will consider using an improvement notice if we decide that it is likely to result in the pharmacy addressing the matters of concern within an acceptable timescale. Where we use an

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2 Section 74D of the Medicines Act 1968
3 Section 74E - Medicines Act 1968
4 Article 13 – Pharmacy Order 2010
improvement notice, we will explain clearly to the pharmacy owner why we consider there is a failure to comply and what they need to do to put it right.

Pharmacy owners are responsible for making sure that the work is carried out within the timeframe set out in the improvement notice. We will give pharmacy owners at least 28 days from the date the notice is served. When we serve an improvement notice, the inspector will contact the pharmacy owner discuss how they can comply.

When we are satisfied that the relevant action has been taken, the notice will be withdrawn and the pharmacy owner will be notified in writing.

If a pharmacy owner fails to comply with the improvement notice, the matter must be referred to the Fitness to Practise Committee. Failing to comply with the terms of an improvement notice can also in some circumstances be prosecuted as a criminal offence in the Criminal Courts.

Any person on who an improvement notice is served may appeal to a magistrates’ court, or in Scotland, to the sheriff5. An appeal may be brought within 28 days beginning with the date on which the improvement notice was served. The Court may suspend an improvement notice pending the determination or abandonment of the appeal.

4.6 As part of our enforcement options, we can also:

• disqualify a pharmacy owner for failing to meet the standards and remove all premises entries from the register6. The legal test to apply this sanction, where registered pharmacy standards are not met, is whether the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively’. This decision will be made by the Fitness to Practise Committee.

• remove one or more premises entries to the register if the Fitness to Practise Committee is satisfied that the pharmacy owner is unfit to carry on the retail pharmacy business safely and effectively.

• impose interim suspension measures in relation to premises entries pending a full hearing of a case or prior to a disqualification or removal direction taking effect7. These decisions are also made by the Fitness to Practise Committee.

5. Criteria for taking enforcement action

5.1 Enforcement action may be escalated at any time and decisions to use enforcement action will be taken on a case by case basis. This will be proportionate and related to the level of risk to pharmacy users and the seriousness of any failure to comply with our standards.

5.2 There are a number of factors that we consider when deciding which enforcement tool or combination of enforcement options to use. These factors include, but are not limited to:

   a. The risk of harm to patients or the public
   b. Compliance with other regulatory or enforcement requirements
   c. The seriousness of the concerns
   d. The willingness and ability of the pharmacy owner to prevent the non-compliance

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5 Article 16 – Pharmacy Order 2010
6 Section 80 – Medicines Act 1968
7 Section 82A – Medicines Act 1968
e. The impact of non-compliance
f. Evidence of repeated or multiple failures to meet our standards
g. Steps taken by the pharmacy owner to prevent non-compliance and any reasons for their failure
h. The ability of the pharmacy owner to address the non-compliance
i. The likely impact of the enforcement action on the registered pharmacy
j. The likely impact on the wider patient community and public
k. The potential for wider learning points for pharmacy owners may mean we will prioritise a single case, so that enforcement sends a broader message to a sector and encourages improvements in the sector
l. Any other relevant considerations
m. The wider public interest

5.3 The weight given to each and any of these factors will be dependent on all the circumstances of the particular case. In all cases we will take into account the wider public interest of any action, including effective use of our resources, and whether such action would align with our wider approach to regulation. Consideration of these factors may result in a change to the type or severity of the enforcement action we intend to take.

5.4 We also consider whether we have sufficient evidence to enable us to proceed to take enforcement action and that this has been recorded appropriately. We follow up on any enforcement action to ensure that improvements are achieved. This includes increasing our level of inspection, where appropriate to do so.

6. What pharmacy owners can expect from us

6.1 Where we require pharmacy owners to take action to remedy any failings, we will:

- clearly explain the nature of the non-compliance(s);
- discuss what is required to achieve compliance, taking into account the specific circumstances,
- clearly explain any advice, actions required or decisions that we have taken;
- give advance notice of our intention to take enforcement action except in cases where we may be required to use urgent procedures;
- agree, wherever possible, timescales that are acceptable to both the pharmacy owner and us, in relation to any actions required;
- provide in writing details of how to appeal against any advice provided, actions required or decisions taken, including any statutory rights to appeal;
- explain what will happen next; and,
- keep in touch with the pharmacy owner where required and until the matter is resolved.
6.2 We welcome approaches from pharmacy owners for advice and clarification on compliance related issues. We will work with you to address any regulatory risk associated with non-compliance that you identify and will take account of your willingness to work with us when considering what action we should take.

7. Other relevant information and legislation

7.1 This policy should be read alongside our other key guidance documents available at:

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[Note: insert any relevant or updated information following the registered pharmacies consultation decision by Council in December 2018]

7.2 We also have legal powers under the Regulation of Investigatory Powers Act 2000 (‘RIPA’). This gives public authorities a clear legal framework to follow if they are conducting surveillance and regulates the way in which investigations are carried out. Its aim is to provide the right balance between protecting privacy and the proper use of data and surveillance to help carry out evidence gathering, in accordance with relevant human rights legislation.

7.3 Under RIPA, we have powers to use directed surveillance (for example monitoring and observing movements or activities) in our investigations, where appropriate. However, we do not have legal powers to use covert human intelligence sources (for example using an informant/ someone acting undercover).

7.4 We will only consider using our powers under RIPA in very limited cases and where all relevant criteria have been met. The use of directed surveillance for a specific investigation must be subject to prior authorisation by a relevant GPhC officer (Director), as specified in Regulations made under RIPA. In all cases, we are required to ensure that any directed surveillance is proportionate, lawful, properly authorised and necessary, having considered relevant and practicable alternatives.

7.5 The use of our powers under RIPA is overseen by the independent Investigatory Powers Commissioners Office (ICPO). The Commissioner, and those that work under the authority of the Commissioner, ensure compliance with the law by inspecting public authorities and investigating any issue which they believe warrants further independent scrutiny. This means that the GPhC is subject to inspection by the ICPO in relation to the use of our powers under RIPA.

[Note: The GPhC has not yet used powers under RIPA. We will be developing a further policy on the use of RIPA powers and the relevant Home Office Codes of Practice for publication in due course]

8 The Investigatory Powers (Codes of Practice and Miscellaneous Amendments) Order 2018

8. Monitoring and review

8.1 We will review how this policy is practically applied and the outcomes of the enforcement action in order to monitor compliance with this policy.
Meeting paper

Council on Thursday, 6 December 2018

Public business

Report of the Gosport Independent Panel

Purpose
This paper provides Council with a brief progress update on our work following the Report of the Gosport Independent Panel

Recommendations
The Council is asked to note the progress update along with our ongoing work in this area

1. Introduction
1.1. The Gosport Independent Panel was set up to address concerns raised by families over a number of years about the initial care of their relatives in Gosport War Memorial Hospital and the subsequent investigations into their deaths. The Panel found that during a certain period at Gosport, there was a disregard for human life and a culture of shortening the lives of a large number of patients by prescribing and administering dangerous doses of a hazardous combination of medication not clinically indicated or justified.

1.2. The full report was published on 20 June 2018 and is available here. The report includes a number of sections outlining how pharmacy services were provided at the hospital and sets out the roles and responsibilities of the pharmacists at the time of the events covered by the report.

2. Taking forward the learnings
2.1. In July 2018, we updated the Council on how we have been working collaboratively and across the organisation to ensure that a comprehensive plan is put together for a co-ordinated response to all the pharmacy and pharmacy regulation issues to which the report relates. At that stage, we provided a high-level summary action plan setting out our key priorities in the short, medium and longer term. We also indicated that we would revise our action plan in light of any official Government report and recommendations expected in the Autumn.

2.2. Since the Council meeting in July, we have completed the following actions:

- Set up a meeting with the RPS and APTUK on 19 September 2018, to discuss the work being carried out by each organisation and to identify any further actions we might
need to take, both individually and collectively.

- Offered to lead a joint piece of work to develop a collective tool, which brings together the key pharmacy themes from the report in one framework along with the existing resources and work under each theme. This is intended to review how current pharmacy arrangements work to prevent a similar situation happening in the future and to enable the pharmacy regulatory and professional leadership bodies to identify any additional necessary actions. This work is due for completion in December 2018.

- Liaised with the Department of Health and Social Care to provide a written progress update for the families affected by the events at Gosport, for the purpose of the family forum meeting on 16 October 2018

- Continued to build our knowledge of what other organisations are doing in response to the report, including sharing information at joint meetings

- Discussed some of the wider themes at a series of four regional roadshows to embed the new emerging concerns protocol. While these workshops were not a direct result of the Gosport report, they touched on important related issues about how regulators can work together to share, at a much earlier stage, information and intelligence that may indicate risks to patients, carers and families or professionals.

2.3. The Government has also now published its official response, which is available [here](#). There are twenty actions outlined across the following three themes: listening to patients, families and staff; ensuring care is safe; and identifying and addressing problems in care. Some of these key actions include:

- The Government will consider how best to strengthen protection for whistle-blowers within the NHS in order to support patients, families and staff to raise concerns.

- CQC is reviewing how it assesses the statutory duty of candour.

- A new Patient Safety strategy to make it easier for staff to report risks and for action to be taken.

- Government commitment to bring forward proposals to reform the framework for professional regulation.

- NHS England review this year on the Controlled Drug Accountable Officer role, local reflection on the Panel Report, and on anticipatory prescribing.
2.4. We published a statement on 21 November to welcome the government’s response and the recommendations for the sector. We will now be carefully considering what this means for pharmacy regulation and our next steps. As the government response outlines, we are committed to working with the pharmacy representative bodies to develop a framework for pharmacy to assess what changes have already been made to help prevent a similar situation to that described in the Panel report happening again and encourage discussion across pharmacy on any further actions that could be taken.

3. **Equality and diversity implications**

3.1. This paper does not raise any specific equality and diversity issues.

4. **Communications**

4.1. We are continuing to monitor the media and parliaments/assemblies, including parliamentary questions, debates and relevant committees across the three countries that we regulate.

5. **Resource implications**

5.1. There are no additional resource implications associated with this work. This will be reviewed in line with any future regulatory action we may need to take in response to the most recent report and recommendations.

6. **Risk implications**

6.1. It is essential that we consider the wider lessons learned, to ensure that we are regulating in a way that continues to be fit for purpose and meets the expectations of the public.

6.2. Strengthening our processes and working collaboratively with others will allow us to fulfil our roles more effectively and identify concerns at the earliest possible stage in the process. Working together can also reduce burdens by encouraging regulators to create joint plans when they share similar concerns.

7. **Monitoring and review**

7.1. We will provide a further update to Council in due course, including the outcomes of our joint work with the professional bodies. This will be in the form of a further progress update at the meeting in February.
Recommendations
The Council is asked to note the progress update along with our ongoing work in this area

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General Pharmaceutical Council

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29 November 2018
Meeting paper

Council on Thursday, 06 December 2018

Public business

Review of Council workshops

Purpose
To provide Council with a six-monthly update on how we have delivered the proposed changes to Council workshops following the review in May 2018.

Recommendations
The council is asked to note this paper.

1. Introduction

1.1. At its meeting in May 2018, Council received a paper from David Prince who had carried out a review of Council workshops. It was agreed that the Executive would draw up a plan for future workshops, taking forward the areas for improvement generated from the review. The areas for improvement covered both the structure and content of workshops, including a desire for more time spent on strategic thinking and external input (while recognising that some flexibility would need to be retained for urgent matters as they arose).

1.2. In the last six months we have begun to implement the changes requested. There has been a demanding agenda of business as usual (BAU) items to be worked through in the limited time available for workshops as well as significant work with Council on the planning and development of our longer-term 10 year vision and strategy. However, we have sought to begin providing sessions with a more outward focus, such as that on demographics and the impact on healthcare at the December meeting, as well as sessions from external subject matter experts for relevant areas of future work.

1.3. This paper considers the workshops held in the second half of 2018 and how they have met the objectives set out in the review. It also sets out a draft forward plan for 2019.

2. Workshops in 2018

2.1. The workshops held since May are summarised in Annex 1, together with the key findings from the review. For reference, those findings were:
• earlier input into strategic and business planning;
• more opportunities for horizon scanning;
• identifying objectives and next steps;
• a mixture of formats (both plenary and table sessions); and
• more external input.

2.2. From the table at Annex 1, members will see that programmes have been circulated for each workshop and information or pre-reading has been included where it was appropriate. Objectives for the workshop sessions have been set out in advance and speakers have been encouraged to outline any next steps at the end of their session.

2.3. Workshops have covered a mixture of business-as-usual topics such as headline findings from consultations as well as more strategic, forward-looking areas such as the ten-year vision and the possible adoption of charitable status. Some topics, such as updates on patient safety issues in the external context and financial modelling, are linked to both BAU and more strategic or forward looking areas. These have been marked as such. In terms of format, we have ensured that there has been an increased mix of plenary and table discussions, or a combination of both.

2.4. Follow-up reports to Council are produced in the form of the Workshop Summary paper which forms part of every Council agenda.

2.5. Throughout the review we have collated feedback from members at the conclusion of the sessions. This has been in the form of feedback cards placed on each table. Whilst not all members have provided feedback, we have received positive and constructive comments. Examples include:

• Welcome the care and thought in setting up the exercises......and the clarity and brevity of presentations
• Very helpful external inputs; provides good basis of knowledge in complex issues
• Structure, format and timing were all good
• Effective use of external speakers on a subject crying out for specialist input
• Getting consensus within small group activities is a good way to temperature check if policy development direction meets members’ vision, individually and collectively
• It’s been helpful to have information in advance to consider opinion before contributing.

2.6. There are some areas on which we will need to continue to improve, including the finding the right balance between incorporating external speakers and continuing to manage our busy programme of BAU within limited workshop time. We also need to ensure that
members continue to be updated on outputs from previous workshops and any links to future work. Between May and December, there has been four sessions linked to external speakers or work, including two sessions with fully external speakers, one with the Clinical Fellows as well as an external speaker on the subject of changing demographics and their impact on healthcare policy and delivery. We have also confirmed a session in February 2019 with the new Chief Executive of the Professional Standards Authority and a wider discussion on the new Standards of Good Regulation.

3. Developing the programme

3.1. If Council is supportive of the changes made so far, we will continue with them while also seeking to make further improvements. In developing the draft programme for 2019, we have focussed on trying to achieve a balance between external speakers and members having early input into significant areas of development or a ‘deep dive’ into a particular area. The draft programme is attached at Annex 2 and members are invited to suggest topics which they would find useful.

3.2. Council workshops are currently held monthly with the exception of January and August. At the Council meeting in November 2018, it was noted that the cycle of both workshops and full meetings of the Council needed to work alongside the business plan so that issues could be given consideration at the appropriate time to allow work to progress. We are considering whether the current timetable of workshops and meetings is the most effective, including looking at what other regulators do (which varies from meeting every month to only meeting quarterly) and looking across the to ascertain times when Council must meet (for example, in May to approve the Annual Report).

3.3. We would welcome comments on the 2019 draft programme and suggestions for other topics, including areas which could be covered at the full-day horizon scanning workshop in May. For example, the review suggested joint sessions with other regulators or key influencers; sessions focussed on Scotland and Wales and consideration of the future role and impact of pharmacy.

4. Equality and diversity implications

4.1. The equality and diversity implications of each topic should be considered both at workshop and formal paper stage. The review did not raise any specific equality and diversity implications, other than support for workshop sessions on areas such as the impact of our EDI work and unconscious bias. A workshop focussed on equality, diversity and inclusion has been scheduled for March 2019.

5. Communications
5.1. The main communication issue raised by the review was a desire for clear objectives and in some cases associated materials to be provided. This has been implemented and will continue. The workshop summary paper which goes to Council puts an outline of the discussions into the public domain.

6. Resource implications

6.1. The main resource implication in the preparation and running of workshops is in staff time. The costs of external speakers are managed within existing budgets and increasing the number of external speakers could have an impact on these, although not all require payment of a fee.

7. Risk implications

7.1. Workshops allow members to develop greater understanding of issues relevant to their strategic and oversight roles, supporting informed decision-making. They therefore play a key role in minimising risk around Council decisions. However, we need to ensure that workshops are optimally designed, so that we can continue to ensure that key BAU is progressed.

8. Monitoring and review

8.1. This paper reviews our progress over the last six months. We will continue to seek feedback from members to support the achievement of the desired outcomes. Given that there is more to do and that we want to maintain momentum in this area, we suggest that it would be useful to review the position again in six to nine months to assure continuing effectiveness.

Recommendations

The Council is asked to note this paper

Laura McClintock, Chief of Staff
General Pharmaceutical Council
Laura.mcclintock@pharmacyregulation.org

Janet Collins, Governance Manager
General Pharmaceutical Council
Janet.collins@pharmacyregulation.org
Tel 020 3713 804

Enter date final version signed-off
Appendix 1

Review of Council Workshops 2018: tracking and evaluation

Below is an outline of how workshops have been carried out based on the new ways of working agreed after the Council review on 10 May 2018.

Annex A sets out the agreed findings and way forward from the review in more detail. The key findings are either incorporated into the table below or have been covered in the paper.

‘Fits with..’ Key: Business as usual: ⬇️ Strategy/Forward look/Horizon scanning: ⬆️

<table>
<thead>
<tr>
<th>Session</th>
<th>Advance programme circulated?</th>
<th>Advance information/ pre-reading circulated?</th>
<th>Objectives given in advance?</th>
<th>Fits with:</th>
<th>External speakers?</th>
<th>Next steps</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>10 May 2018 – all day workshop</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>BaU</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Aligning our regulatory strategy with our organisational and financial strategy</td>
<td>Yes</td>
<td>Background reading and table exercise instructions</td>
<td>Yes</td>
<td>Strategy</td>
<td></td>
<td></td>
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<tr>
<td><strong>7 June 2018</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Exploring adopting charitable status</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>BaU</td>
<td>Yes Abbie Rumbold (Bates, Wells and Braithwaite solicitors) and</td>
<td>Yes</td>
</tr>
<tr>
<td>Session</td>
<td>Advance programme circulated?</td>
<td>Advance information/pre-reading circulated?</td>
<td>Objectives given in advance?</td>
<td>Fits with:</td>
<td>External speakers?</td>
<td>Next steps</td>
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<td></td>
<td></td>
<td>BaU</td>
<td>Strategy</td>
<td></td>
</tr>
<tr>
<td>Brief oral update on the current registered pharmacies consultation</td>
<td>No</td>
<td>n/a</td>
<td>n/a</td>
<td></td>
<td>Steve Downs (GMC)</td>
<td>Yes</td>
</tr>
<tr>
<td>12 July 2018</td>
<td>Investments and risk appetite</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td>Yes</td>
<td>Andrew Hunter Johnson and Daisy Mannifield (CCLA)</td>
</tr>
<tr>
<td>Initial findings from Pharmacist independent prescriber consultation</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Continuing our development of a ten-year vision</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>13 September 2018</td>
<td>Update on development of ten-year vision</td>
<td>Yes</td>
<td>Briefing paper</td>
<td>Progress update</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Interactive financial model exercise</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>Session</td>
<td>Advance programme circulated?</td>
<td>Advance information/pre-reading circulated?</td>
<td>Objectives given in advance?</td>
<td>Fits with:</td>
<td>External speakers?</td>
<td>Next steps</td>
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<td>BaU</td>
<td>Strategy</td>
<td></td>
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<tr>
<td>Pharmacist IET standards</td>
<td>Yes</td>
<td>n/a</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>Yes</td>
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<tr>
<td>11 October 2018</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>Governance and regulation of post-registration education and training</td>
<td>Yes</td>
<td>n/a</td>
<td>Progress update</td>
<td></td>
<td>No</td>
<td>n/a</td>
</tr>
<tr>
<td>Engaging on our ten-year vision</td>
<td>Yes</td>
<td>No</td>
<td></td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Registered pharmacies consultation headlines and next steps</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>8 November (shorter workshop due to long agenda for main meeting)</td>
<td></td>
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<tr>
<td>Update from clinical fellows</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Patient safety issues in the external context</td>
<td>Yes</td>
<td>No</td>
<td>n/a</td>
<td></td>
<td>No</td>
<td>n/a</td>
</tr>
<tr>
<td>6 December 2018</td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Changing demographics and their impact on healthcare</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td></td>
<td>Yes – Tom Johnson</td>
<td></td>
</tr>
<tr>
<td>FtP future legislative framework</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>Outline budget and priorities 2019-20</td>
<td>Yes</td>
<td></td>
<td>Yes</td>
<td></td>
<td>No</td>
<td>Yes</td>
</tr>
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</table>
Annex A: Key findings from the review

Purpose of workshops

a. **Strategic review and horizon scanning.** Members sought earlier input to strategic and business planning, with more opportunity for ‘blue sky’ thinking and horizon-scanning. We support this direction of travel and we will seek to achieve a better balance between ongoing work streams/business as usual and wider strategic review. This is linked to the principle that we continue to do as much as we can in the formal Council meetings, which may reasonably include discussion of some early strategic and policy proposals. Additionally, we will build in time for one or two sessions per year that focus only on wider strategic review/ horizon scanning, the first of which is scheduled for 10 May 2018.

b. **Identifying objectives /next steps:** Members sought improved clarity on the objectives of individual sessions, expected outcomes and any agreed direction of travel or next steps. Members also felt that it is timely to refocus and highlighted a need for better connectivity and linkage between workshops and workstreams. Going forward, we will ask presenters to be clearer about their expectations of the session or task from the outset (potentially with a short outline included on the workshop Agenda which is circulated in advance), and to set out agreed next steps. We will also seek to build in more evaluation, looking back and forwards more often on achievement and direction.

Structure and design

c. **Format:** Members were in support of receiving presentations and other materials in advance, to enable increased discussion time on the day. There were also suggestions about how to improve the mix of plenary and table discussion, and how best to use the available time on the day. We will be taking forward these ideas with relevant staff, to ensure that workshop time is maximised and that members get the most from the sessions.

d. **External input:** Members were universally in support of more frequent external input on matters with wider public interest, to help assess the impact of policy changes, spot emerging regulatory risk and learn about developing practice in other areas. Other suggestions included occasional joint meetings with relevant stakeholders and other regulatory bodies.

e. **Setting agendas:** We recognise and support the demand for increased member input into the workshop forward plan, and the early development of policy and strategy proposals. We are considering how we can incorporate the feedback from the review into the existing forward plan and increase the levels of external input. At Appendix A is a broad outline of the key sessions that we intend to cover over the next 9-12 months. We have focused on key
workstreams and themes, as we need to retain some flexibility on timings due to factors such as pre-planned decision points for Council meetings, and availability of speakers. However, we welcome suggestions for external speakers and additional agenda items.
### Plan for Council Workshops 2019

**Key:** Business as usual:  
Strategy/Forward look/Horizon scanning:

<table>
<thead>
<tr>
<th>Month</th>
<th>Workshop topics</th>
<th>Links to:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>February</strong></td>
<td>Professional Standards Authority – meet the new Chief Executive and discuss the new Standards of Good Regulation</td>
<td>Strategic relationships; Strategic planning; PSA Annual review</td>
</tr>
<tr>
<td></td>
<td>Balanced scorecard – including a themed report example</td>
<td>Performance monitoring; Business planning</td>
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<tr>
<td><strong>March</strong></td>
<td>Equality, Diversity and Inclusion – where does the GPhC want to be? Discussion with Council on discrimination and what the Council sees as priorities in this area</td>
<td>Culture change; Strategic planning</td>
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<tr>
<td></td>
<td>Developing a fees strategy</td>
<td>Strategic planning; Business planning;</td>
</tr>
<tr>
<td><strong>April</strong></td>
<td>Developing an accommodation strategy</td>
<td>Strategic planning; Business planning;</td>
</tr>
<tr>
<td><strong>May – full day</strong></td>
<td>Horizon scanning and forward look – mixture of external and internal presenters</td>
<td></td>
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<tr>
<td></td>
<td>NB – consider whether extend to 1.5 days</td>
<td></td>
</tr>
<tr>
<td><strong>June</strong></td>
<td>New Pharmacists – challenges and opportunities – BPSA?</td>
<td>Understanding the range of clinical practice; Strategic relationships</td>
</tr>
<tr>
<td><strong>July</strong></td>
<td></td>
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</tr>
<tr>
<td>Month</td>
<td>Content</td>
<td></td>
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<tr>
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<tr>
<td>September</td>
<td>Clinical fellows – outcomes of their work and reflections on their year at the GPhC</td>
<td></td>
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<tr>
<td>October</td>
<td>Budget and business planning</td>
<td></td>
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<tr>
<td>November</td>
<td></td>
<td></td>
</tr>
<tr>
<td>December</td>
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