General Pharmaceutical Council

Council meeting

10 May 2018

10:00 to 11:00 **approx.**
Council Room 1, 25 Canada Square, London E14 5LQ

Public business

1.	**Attendance and introductory remarks**	Nigel Clarke
2.	**Declarations of interest** *Public items*	All
3.	**Minutes of last meeting** *Public session on 12 April 2018*	Nigel Clarke
4.	**Workshop summary – 12 April 2018**	Nigel Clarke
5.	**Actions and matters arising**	Nigel Clarke
6.	**Review of Council workshops: Next steps** *For noting*	*18.05.C.01* David Prince
7.	**Ensuring a safe and effective pharmacy team** *For approval*	*18.05.C.02* Priya Warner
8.	**Any other public business**	Nigel Clarke

Confidential business

9.	**Declarations of interest** *Confidential items*	All
10.	**Minutes of last meeting** *Confidential session on 12 April 2018*	Nigel Clarke
11.	**Confidential actions and matters arising**	Nigel Clarke
12.	**Any other confidential business**	Nigel Clarke

Date of next meeting

Thursday, 07 June 2018

General Pharmaceutical Council

Minutes of the Council meeting held on Thursday 12 April 2018 at 25 Canada Square, London at 13:30

TO BE CONFIRMED 10 MAY 2018

Minutes of the public session

Present

Nigel Clarke (Chair)

Mary Elford

Digby Emson

Mark Hammond

Mohammed Hussain

Joanne Kember

Alan Kershaw

Elizabeth Mailey

Arun Midha

Berwyn Owen

David Prince

Samantha Quaye

Jayne Salt

Apologies

Evelyn McPhail

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 (Interim Director of Education and Standards)

Laura McClintock (Chief of Staff)

Pascal Barras (Interim Head of Governance)

Priya Warner (Head of Policy and Standards)

Helen Dalrymple (Council Secretary)

1. Attendance and introductory remarks

1.1. The Chair welcomed all present to the meeting. Apologies had been received from Evelyn McPhail.

2. Declarations of interest

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

3. Minutes of the last meeting

3.1. **The minutes of the public session held on the 8 March 2018 were confirmed as a fair and accurate record.**

4. Workshop summary – 8 March 2018

4.1. Members enquired as to how this item would change following the review of Council workshops that was currently underway. David Prince (DP), who was conducting the review, replied that it was too early to answer this question but that all members had indicated that in the future they would like emphasis on follow-up.

4.2. **Council noted the discussions from the workshop.**

5. Actions and matters arising

5.1. Action minute ref. 31.6: The comments section was updated to clarify that this work would come to Council in September.

5.2. Action minute ref. 95.2: This information would be circulated to members shortly. DR said that any inefficiencies of cancelled hearings would be addressed with ongoing work around efficiency and effectiveness.

6. Consultation on developing our approach to regulating registered pharmacies

6.1. Claire Bryce-Smith (CBS) presented **18.04.C.01**. This paper presented a consultation document on developing the organisation's approach to regulating registered pharmacies and the introduction of the publication of reports from inspections of registered pharmacies.

6.2. Mohammed Hussain declared an interest as a pharmacy owner.

6.3. Members commented on structure of the document in that it had a long introduction setting out the background of engagement in this area. They suggested moving the key proposals to the front of the consultation to maximise engagement. CBS explained that context was important and there was a balance to be struck in explaining the history.

6.4. There would now be a link to a proposed inspection report in the consultation, which would provide more context and assist with questions on format.

6.5. CBS agreed that it would be a good idea to refer to the benefits of publishing aggregate as well as individual inspection reports.

6.6. Members discussed what visibility should be given to our new enforcement powers. They were not being consulted on but could provide the public with some level of assurance. This would be considered, remembering the importance of balance and context, and the consultation document will reference that we will be developing an enforcement policy in due course.

6.7. Members asked whether there would be an independent appeals process. CBS said that there would in terms of another inspector reviewing the inspection, but not in terms of an external organisation. This was in line with other regulators.

6.8. Council identified an area of concern around what would happen to premises following a 'not met' rating. They agreed that the narrative in the consultation should be clear on this and set out what powers the GPhC had to take further action. The consultation should invite comment on the impact of all of the proposals so the repercussions of being rated 'not met' and inspection reports being published were more clearly understood.

The issue of enforcement was important. The consultation should explain that when a 'not met' rating was issued, an action plan would be drawn up and that if this was not adhered to then enforcement action would follow. It was highlighted that statutory enforcement powers would be reserved for those situations where a pharmacy owner does not complete an action plan and undertake the necessary changes to ensure that our standards are met, or for those situations where there is a serious risk to patient safety. Either way, there will be a formal process to follow via the fitness to practise procedures.

6.9. It was agreed that adding some examples to bring various situations to life could be helpful, with a spectrum from minor non-compliance to the very serious along with what the consequences might be. A new section could be added on enforcement explaining how premises were held to account when they did not meet the standards.

6.10. There was discussion around what would happen if an inspection was announced on a day that was particularly busy. If the pharmacist or pharmacy technician were diverted from their job to facilitate the inspection this may compromise their ability to deliver services safely.

6.11. It was agreed that the narrative should be expanded to provide assurance on this. CBS explained that the inspector did not have to be alongside the pharmacist or pharmacy technician for much of the inspection. It was important, however, to uncover any issues around capacity and low staffing levels.

6.12. Members asked about the knowledge hub referred to in the consultation. They emphasised that is was important to be clear on whose responsibility it would be to keep it up to date. CBS said that this was in the early stages of development. Work was ongoing, but it would be kept efficient and effective.

6.13. Council considered the impact that a negative result in inspection and that result being published would have on commercial interests. CBS replied that public and patient focus groups had not seemed too concerned with using premises that had not met the standards. They were reassured that they had been assessed and that there was an action plan in place. The Council should acknowledge the risk for an owner in publicly not meeting the standards.

6.14. Members discussed the terminology of inspections. Some were not comfortable with the binary choice between 'met' and 'not met' and they asked that the consultation document invite respondents to suggest other ways to convey this. DR reassured Council that he realised that a strong steer had been given here and that it would be dealt with. There was opportunity for respondents to the consultation to do this. In the meantime, the momentum of the consultation had to be maintained.

6.15. Council asked that consideration be given to including a question about GPhC powers in the consultation.

6.16. The Chair summarised that Council asked that some changes were made to the document before approval. These changes would include:

- a point on aggregate learning from inspections

- more narrative making the point that the inspector will not get in the way of the pharmacy team providing services safely

- a potential further question on our powers of enforcement

- a potential further question on the public's reaction to a 'not met' outcome

6.17. Once made the revised consultation document with highlighted changes would be circulated to Council members. Further amends may be made following comments and the document would then be signed off by the Chair.

6.18. **Council:**

> i. Agreed for consultation proposals on developing an approach to regulating registered pharmacies and introducing the publication of reports from inspections of registered pharmacies.
>
> ii. Agreed to delegate final approval of the consultation document to the Chair.

7. Reviewing our publication and disclosure policy

7.1. Priya Warner (PW) presented **18.04.C.02**. This paper updated Council on the review of the publication and disclosure policy.

7.2. Members welcomed the paper and asked for assurance that the organisation would meet the requirements of the General Data Protection Regulation (GDPR) that would come into effect in May 2018. Digby Emson, Chair of the Audit and Risk Committee, said that the committee had been kept up to date and that the review of the publication and disclosure policy was part of the process of adhering to the GDPR.

7.3. It was important to get the view of both registrants and the public in this consultation, the rights of the public to information had to be balanced with those of the individual.

7.4. An interim summary of the implementation of the GDPR would be circulated to members so that they could be assured that this important work was on track.

ACTION: CBS

7.5. **Council noted the paper.**

8. Safe and effective pharmacy teams

8.1. Mark Voce (MV) presented **18.04.C.03.** This paper set out how assurance was provided to the public that there were enough staff, suitably skilled and qualified, for the safe and effective provision of pharmacy services at registered premises.

8.2. Council asked how the effectiveness of staffing plans put in place by pharmacy owners could be measured. They wanted to know whether there was any mechanism in place for the GPhC to assess whether they were working well. MV agreed that the test would be for inspectors to look at the plan in operation. Anyone working in the pharmacy should know about the plans and how they could raise a concern if they were not effective.

8.3. CBS said that another avenue may be with the Strategic Relationship Managers (SRMs) of larger pharmacy owners.

8.4. Members acknowledged the tension between businesses needing to remain open and the registrant's concern at whether it was safe to do so. Any pharmacist or pharmacy technician should feel able to raise a concern without fear of repercussions. MV agreed

and acknowledged that these situations may be difficult to tease out. The guidance would be explicit in its expectations here though and it was a step forward in the right direction.

8.5.   Council made the following drafting points:

- At 3.3 it should be added that the staffing plan should take account of the changing business profile throughout the day

- Also at 3.3 concerns raised about staffing levels should always be recorded so that there is a note of their occurrence and other staff are aware.

- At 3.5 the volume of prescriptions should be assessed and whether they were done internally or externally as well as any other services provided. This would give a good idea of the profile of the pharmacy business.

8.6.   The methodology of inspection would not expect inspectors to analyse the staffing plan. They would ask to see it and test it with questions on the ground. DR said that there would be guidance on what would be acceptable. There may be a role here for professional bodies in assisting registrants with developing best practice.

8.7.   Council asked that any guidance be clear that it referred explicitly to community pharmacy.

8.8.   **Council noted:**

   i.   **The way assurance was provided to the public about whether pharmacy owners were meeting the standards for having sufficient staff at registered pharmacies;**

   ii.   **That new guidance to be provided to pharmacy owners was being prepared; and**

   iii.   **How inspections assess whether there were sufficient staff and the action taken where staffing levels were insufficient**

9. Any other public business

9.1.   There being no further public business to discuss the meeting closed at 15:10

Date of the next meeting:

Thursday 10 May 2018

Meeting paper

Council on Thursday, 10 May 2018

Public business

Council Workshop Summary

Purpose

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

Recommendations

The Council is asked to note the discussions from the workshop

1. Introduction

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

- interact with and gain insights from staff responsible for delivering regulatory functions and projects;

- receive information on projects during the development stages;

- provide guidance on the direction of travel for work streams via feedback from group work or plenary discussion; and

- receive training and other updates.

1.2.   Following each workshop there 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.

2. Summary of the April workshop

2.1.   *Update on exiting the European Union*

Members heard that there was a lot of uncertainty around the impact that leaving the EU would have on the delivery of health care. One of the key issues was that of workforce. Numbers of EEA applications had dropped since Q4 of 2016/17. However, it was noted that currently the numbers of pharmacists and pharmacy technicians on our register who trained in other EEA countries were low. The future of the EU directive on the mutual recognition of professional qualifications was discussed and how that would potentially affect UK training as well as the current overseas pharmacist adaptation programme (OSPAP). The Council will continue to discuss and plan for the implications of Brexit.

2.2. *Developing standards for pharmacist initial education and training (IET)*

There was discussion of plans to review the standards for pharmacist initial education and training (IET) which were due for review. The current standards were issued in 2011 and there had been significant changes in education in that time, including difference across Great Britain. It was noted that a significant amount of pre-consultation work has been carried out into how the standards could be updated; independent research suggested that 95% of those asked had indicated that they felt that some or significant change to IET was needed. At one point the discussion focused on five-year integrated degrees and whether members felt that this would be an appropriate way of updating the standards.

This discussion would be fed into the work on preparing for the consultation on IET due later this year.

2.3. *Future of fitness to practise (FtP)*

A discussion was held about developing our approach to fitness to practise. A recent Professional Standards Authority (PSA) conference had indicated an appetite for change throughout regulators. Council talked about how to move away from the lengthy and inflexible fitness to practise procedures towards a more restorative approach, supporting remediation and a culture of learning and reflection.

This would inform the development of a wider strategy and vision around how we regulate as well as defining the principles that will guide our work.

2.4. *Online pharmacies*

Members were given an update on our approach to regulating online pharmacies. Change was fast paced in this complex area and it was important to assure Council that we were doing as much as possible to protect the public.

The GPhC was working with other regulators such as the Care Quality Commission (CQC) and the Medicines and Healthcare products Regulatory Agency (MHRA) as well as sharing

information and enhancing MOU information-sharing agreements. The inspection model was being improved. The guidance for distance selling was being reviewed. There were a number of FtP cases at the moment involving online pharmacies and there were ongoing discussions with the Department of Health and Social Care about regulatory gaps.

Recommendations

Council is asked to note the discussions from the workshop

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4 May 2018

Council actions log

Meeting date	Ref.	Action	Owner	Due date	Status	Comments/update
6 Jul 2017	31.6	**Consultation on revised threshold criteria:** A report on equality, diversity and inclusion in Fitness to Practise processes would be brought to Council in due course.	Claire Bryce-Smith	Sep 18	Open	This report will be commissioned externally and will go out to tender in Jan/Feb 18. Once commissioned it is anticipated that it will take at least three months to produce the report.
	59.9	**Registration assessment and Board of Assessors' Report – June and September 2017:** Wider data and policy issues around the Registration Assessment would be picked up in a paper to Council from the executive, out of the current reporting cycle.	Mark Voce	Jun 18	Open	
	84.14	Members said that they would like to see more detail in the management accounts with underlying figures in tabular form	Megan Forbes	Jun 18	Open	
8 Mar 2018	95.2	Information on the costs of cancelled hearings would be circulated to Council members in April	Francesca Okosi	Apr 18	Open	
12 Apr 2018	7.4	An interim summary of the implementation of the GDPR would be circulated to members	Claire Bryce-Smith	Jun 18	Open	

Meeting paper

Council on Thursday, 10 May 2018

Public business

Review of Council workshops: next steps

Purpose

To update Council on the Review of Council workshops and the proposed way forward

Recommendations

The Council is asked to note the key findings from the review alongside the proposed way forward

1. Introduction

1.1. The Council holds a workshop session alongside its formal Council meetings each month, with the exception of January and August. The workshops give Council 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, a summary of the discussion is prepared and presented at the subsequent meeting. This makes the development process of our work streams more visible to the GPhC's stakeholders although some confidential items may not be reported on in full. The Council does not make decisions in the workshop sessions. They are informal discussions to aid the development of the Council's views. Policy and other matters are determined, after full debate and scrutiny, in open meetings of the Council.

Review of the workshops

1.3. In February 2018, we commenced a review of the workshop processes and operations. This review was initiated by the Chair of Council and the Chief Executive and Registrar, and led by David Prince, Council member.

1.4. Whilst the scope of the review was broad, we started from the position that workshops continue to be a valuable part of the way we work. Council members were not constrained to answering specific questions, but instead invited to provide open feedback and comments on the future purpose, structure and design of workshops.

1.5. As to the purpose of the workshops, members were asked to consider matters such as the mechanisms we have for reflection about strategic direction and horizon planning, early discussion of future work streams and input from key external stakeholders or others. On structure and design, members were asked to think about our current style of working, the balance of formal Council Meetings and workshops; the format of the workshop discussions, and next steps and forward planning.

2. Key considerations

2.1. At the end of the review period, members' responses were collated, summarised and circulated.

2.2. Members were unanimously in favour of retaining the workshops, noting that they provide a valuable opportunity for to develop greater understanding of relevant issues, which in turn supports and contributes to informed decision-making in the appropriate forum. The sessions enable members to take a closer look at work in development and to input into the wider strategic development of the organisation. They are also seen as an effective two-way communication between members and the Executive. However, members identified a number of areas for improvement relating to both purpose and design. In particular they sought a clearer line of sight to the upcoming programme, its linkages to strategic and business plans and how the outcome of workshops had contributed to work streams. With this is a wish for fuller summaries of the discussions of each workshop, to be circulated soon after meetings so as to prompt reflections and feedback.

2.3. Below is a brief summary of the key findings from the review alongside our proposed way forward.

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.

f. **Electronic support for members:** There were various suggestions for access to document libraries, e-forums, etc. to continue discussions and reflections and it may be incoming new members will have greater expectations in this area. It will be considered when developing the Transformation programme.

3. Equality and diversity implications

3.1. We are committed to promoting equality, valuing diversity and being inclusive in all our work. The review did not raise any specific equality and diversity implications other than support for specific workshop sessions on areas such as the impact of our EDI work and unconscious bias. We will be exploring how to include these themes in future workshop sessions.

4. Communications

4.1. The review did not raise any specific communications implications, other than those issues set out in the summary above.

5. Resource implications

5.1. The costs associated with Council workshops are provided for in existing budgets. Increasing the number of external speakers could potentially have an impact on these costs. However, for some external speakers, associated costs may be nil or limited to expenses only. We will continue to monitor the likely impact as we proceed and aim to manage these costs within existing budgets.

6. Risk implications

6.1 It is essential that workshops are carried out in a way that enables members to fulfil their important oversight role and provides an opportunity to develop greater understanding of relevant issues, which in turn supports and contributes to informed decision-making in the appropriate forum. The feedback from this review is being taken forward with immediate effect, where possible, and we will continue to evaluate progress in this area.

7. Monitoring and review

7.1. In six months, we propose to carry out an evaluation of how workshops have impacted on the developing work programme.

Recommendations

The Council is asked to note the key findings from the review alongside the proposed way forward

David Prince, Council member

Laura McClintock, Chief of Staff

General Pharmaceutical Council

4 May 2018

Draft plan for Council workshops

Over the next six to nine months we already have a number of 'business as usual' items on the plan for discussion at Council workshops. These include:

Pharmacist independent prescribers
Registered pharmacies
Publication and disclosure policy
Initial education and training for pharmacists

In the next year we will also aim to have several sessions with input from external stakeholders. These will include bodies such as the Professional Standards Authority (PSA), representative bodies for pharmacists and pharmacy technicians, Chief Pharmaceutical Officers, healthcare commentators and Pharmacy Schools.

Themes of sessions aligned more to 'blue sky thinking' and setting strategy have been considered and we anticipate that we will hold sessions on these topics:

Pharmacy in the digital age
How the demographics of public and patients in the UK are likely to impact healthcare
Updates from inspectors – 'stories from the frontline'
The role of pharmacists and technicians in healthcare and prescribing within the developing bigger picture of healthcare delivery

This list is not exhaustive, and some flexibility will need to be retained to allow for urgent matters to take priority occasionally.

We will also include a 'forward' look of the workshops in each summary report presented to Council meetings.

Meeting paper

Council on Thursday, 10 May 2018

Public business

Ensuring a safe and effective pharmacy team

Purpose

To provide Council with the revised guidance for pharmacy owners to ensure a safe and effective pharmacy team and the proposals for taking forwards education-related work for unregistered pharmacy staff.

Recommendations

The Council is asked to:

(1)   Agree the revised guidance for pharmacy owners to ensure a safe and effective pharmacy team (Appendix 1);

(2)   Agree the proposals for taking forwards the education-related work for unregistered pharmacy staff; and

(3)   Note the equality impact analysis (Appendix 2).

1. Introduction

1.1   Between 20 July and 11 October 2017, we consulted on new draft guidance for pharmacy owners which outlined what they are expected to do to ensure everyone in the pharmacy team can provide safe and effective services to users of pharmacy services. The purpose of the consultation was to receive formal feedback on the draft guidance and on our proposed updated policy framework.

1.2   We proposed that:

   a)   the pharmacy owner should be accountable for the training of unregistered staff in their pharmacy, instead of the individual pharmacist, as is currently the case;

   b)   the GPHC would no longer accredit and recognise courses and training programmes;

   c)   we would produce draft guidance for owners to ensure the safe and effective pharmacy team and the guidance would replace the minimum training policy (MTP);

d) staff who are involved in dispensing and supplying medicines must have the knowledge and skills of the relevant units of a nationally-recognised Level 2 qualification, or be training towards this;(removal of equivalence)

e) unregistered staff who need further education and training to meet the required competency level for their role should be enrolled on an appropriate training programme within three months of commencing in their role.

1.3 Council noted the consultation report in March 2018 which included a detailed summary of the feedback on the proposed policy framework and the draft guidance.

1.4 We heard:

- the majority of respondents agreed with our proposal that the pharmacy owner, instead of the pharmacist should be responsible for making sure that unregistered staff have the appropriate training and are competent for their roles.
- a large majority of respondents thought the guidance included the areas that pharmacy professionals would expect to ensure a safe and effective pharmacy team, but some respondents expressed a view that the guidance did not address all relevant issues or provide sufficient detail on these, in particular on staffing levels.
- there were mixed responses regarding the proposals for unregistered staff to have the relevant knowledge and skills of a nationally-recognised Level 2 qualification and the commencement of training within three months. Some respondents felt that the training requirements provided a level of consistency and standardisation but did not fit in with our outcome focussed approach as it was too prescriptive and did not allow for equivalent courses or exemptions. It was thought that the GPHC courses provided assurance for employers.
- concern was expressed about the GPhC's withdrawal from the accreditation of courses and the potential decline in the standard of courses. Respondents felt the current system was working well and was well understood by everyone. They believed the quality assurance function should be retained, and if the GPhC were to withdraw from this, then another reputable organisation should step in and provide this level of assurance.

2 Education and training framework for unregistered pharmacy staff

2.1 One of the key ways we deliver the aims in our strategic plan is by setting standards for the (initial) education and training of registrants and by quality assuring its outcomes.

2.2 Council has identified education and training as a priority area and we have developed an ambitious education development programme to support the delivery of new standards in this area and to revise our approach to education quality assurance.

2.3 Given this work, we propose that the education-related work for unregistered pharmacy staff is taken forward as part of the education development work. This will ensure that the principles and approach to all of our education and training, and quality in education, is aligned.

2.4 Subject to Council's agreement we will retain the current policy, in relation to minimum training requirements and will continue to approve courses and training programmes until such time that the education development programme looks at this area in further detail.

3 Guidance for the safe and effective pharmacy team

3.1 This work is closely aligned with our strategic aim to support and improve the delivery of safe, effective care and uphold trust in pharmacy by ensuring that the pharmacy team have the necessary knowledge, attitudes and behaviours. As we committed to in our Strategic plan 2017-20, our draft guidance emphasises the whole pharmacy team's contribution and their role in quality and improvement.

3.2 The guidance for ensuring a safe and effective pharmacy team has been revised in light of feedback from the consultation and has been reviewed by the Word Centre. It is included in Appendix 1.

3.3 The guidance now reflects proposals outlined in an April 2018 Council paper, where we explained to Council how we would address staffing levels in the guidance and how we would provide assurance that the pharmacy team was providing safe and effective care.

3.3 We have:

   a) revised the section about accountability and the respective roles of the pharmacy owner, board, responsible pharmacist and the wider team to provide greater clarity (See Accountability section in the guidance);

   b) strengthened what the guidance says about staffing levels, and made this a separate section within the guidance (See section 1 of the guidance);

   c) retained the requirement for competence to a level equivalent to a nationally recognised level 2 in England and Wales, or a level 5 in Scotland (see section 4 of the guidance); and

   d) improved the language, tone and structure of guidance taking on board what we have heard

4 Equality and diversity implications

4.1 Our equality impact analysis work has been informed by our qualitative and quantitative analysis of responses to the consultation and the available evidence relating to groups by reference to protected characteristics, in line with our responsibilities as set out in the Equalities Act 2010.

4.2   The equality impact analysis identifies the impact of all the proposals in the consultation on ensuring a safe and effective team. Primarily the impact on equality and diversity was related to the education and training proposals, which we do not propose to take forwards at this stage.

4.3   The equality and diversity implications of the draft guidance are included in the full analysis presented to Council. We have not identified any further equality and diversity implications that have not already been addressed.

5   Communications

5.1   Subject to Council approval, the draft guidance to ensure a safe and effective pharmacy team will be promoted to pharmacy owners, and the pharmacy team via a range of communications channels. The guidance will also be published on our website alongside our existing suite of guidance to support the standards for registered pharmacies and be available on our mobile phone app. We anticipate publishing the guidance in June 2018.

5.2   We will also write to course and training providers so that they are aware of our decision in relation to accreditation of courses.

6   Resource implications

6.1   The resource implications for this work, including communication and implementation of the new guidance, have been accounted for in existing budgets.

7   Risk implications

7.1   The guidance is closely aligned with our strategic objectives and it is important that it reflects Council's commitment to recognising the valuable contribution of the whole pharmacy team, whilst ensuring the delivery of safe and effective care and pharmacy services.

7.2   It is important that we are able to communicate clearly why Council has made its decisions, as this will assist in communicating and explaining any changes to the guidance.

8   Monitoring and review

8.1   The guidance to ensure a safe and effective pharmacy team, once approved, will be reviewed as and when appropriate or when there are changes to our Standards for Registered Pharmacies and the Inspection Decision Framework.

Recommendations

The Council is asked to:

(1) Agree the revised guidance on ensuring a safe and effective pharmacy team (Appendix 1);
(2) Agree the proposals for taking forwards the education related work for unregistered pharmacy staff; and
(3) Note the equality impact analysis (Appendix 2).

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4 May 2018

Guidance for pharmacy owners to ensure a safe and effective pharmacy team

About this guidance

This guidance explains what the pharmacy owner[1] should do to ensure a safe and effective pharmacy team and meet the standards set out under Principle 2 of the standards for registered pharmacies. The guidance is for pharmacy owners, who are responsible for making sure the whole pharmacy team – both registered pharmacy professionals and all unregistered staff – provide safe and effective care and pharmacy services.

You should read this guidance alongside our **Standards for registered pharmacies**, which pharmacy owners must meet, and our **Inspection decision-making framework**.

As the pharmacy owner, you are responsible for making sure this guidance is followed. Everyone in the pharmacy team should be familiar with the guidance, including managers with delegated responsibility. If the registered pharmacy is owned by a 'body corporate' (for example a company or an NHS organisation) you should make the superintendent pharmacist aware of this guidance and they should make sure it is followed.

You must also be familiar with our **Standards for pharmacy professionals** and the **guidance** we have published on our website to help pharmacy professionals apply our standards and meet their professional obligations.

We also believe this guidance may be helpful for other organisations who employ pharmacy professionals or provide pharmacy services across a range of settings – for example hospitals and industry – although we do not regulate all these settings.

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[1] A pharmacy owner may be a registered pharmacy professional; a pharmacist as a sole trader, partner or director, or a pharmacy technician as a partner or director in Scotland; or may be unregistered as a partner or a director in Scotland; or a 'body corporate'.

Introduction

Every member of the pharmacy team provides a vital service to patients and the public. Although registered pharmacies may have different ownership structures, it is important that the culture and processes within the pharmacy deliver safe and effective care to patients and the public.

A pharmacy owner's first responsibility is to ensure patient safety. In practice, this means making sure:

- each pharmacy has enough skilled and qualified staff to provide safe and effective pharmacy services
- staff can meet their professional obligations and can raise concerns in an environment which encourages openness, honesty and continuing development.

The needs of people who receive care from registered pharmacies, and the way pharmacy services are provided, continue to evolve and change. As such, the roles needed to deliver pharmacy services are developing to reflect these changes. Training and development for pharmacy teams should be flexible in responding to these changes, to give staff in the team the knowledge and skills to meet the new challenges and opportunities they face. Owners need also to continually assess staffing levels and the appropriateness of the skills mix within the pharmacy to ensure patient safety.

Effective team working is an essential part of providing good-quality, person-centred care. Pharmacy owners and pharmacy professionals are best placed to identify the needs of patients and the public, and the training and development their teams need to deliver person-centred care and remain competent in the interests of their patients. They also have a shared responsibility to make sure that any member of staff involved in the sale and supply of medicines has the knowledge and skills to carry out their tasks safely and effectively. This includes unregistered staff, who are often the first point of contact with patients and the public.

Accountability

Pharmacy owners

Pharmacy owners are responsible for ensuring the safe and effective provision of pharmacy services from a registered pharmacy. They are accountable for making sure that the standards for registered pharmacies are met. If the pharmacy is owned by a body corporate, the directors must assure themselves that the standards for registered pharmacies are being met.

As a pharmacy owner you should consider the context of each individual pharmacy. This includes:

- the range of services provided
- the skill mix and number of staff in the pharmacy team
- most importantly, the needs of patients and people who use pharmacy services.

You should use the resources you have (which includes staff and their skill mix) to ensure safe and effective outcomes for patients. You must also make sure your staff have the necessary training appropriate to their roles.

Your own accountability does not affect the important responsibility of individual pharmacy professionals to contribute to the education, training and development of the team or of others, and to promote and encourage a culture of learning and development.

Leadership and management roles

We realise that for anyone operating a registered pharmacy there will always be competing demands. These may be professional, managerial, legal or commercial. However, medicines are not ordinary items of commerce. Along with pharmacy services, the supply of medicines is a fundamental healthcare service.

In a limited, or public limited company, the board of directors has a significant role in making sure people receive safe and effective care from registered pharmacies. The Companies Act, and other relevant legislation, sets out the legal responsibilities for directors. In a pharmacy where healthcare is being delivered to the public, there is further guidance[2] for directors about their extra responsibilities in delivering a public service. This applies whether they are in a private or a voluntary organisation.

2

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/4815 35/6.1291_CO_LAL_Ethical_standards_of_public_life_report_Interactive__2_.pdf

Staff in leadership or managerial roles, such as branch or area positions, may be pharmacy professionals or unregistered. Given the role they also play in the way pharmacy services are developed and delivered, the guidance also includes particular advice for all those who work in leadership and management roles.

Pharmacy professionals

Registered pharmacists and pharmacy technicians are regulated professionals and must meet the standards for pharmacy professionals. This includes demonstrating leadership when providing safe and effective care. Pharmacy professionals should contribute to the education, training and development of the team, or of others, and must delegate tasks only to people who are competent and appropriately trained or in training. They must also exercise proper oversight.

Pharmacy professionals should have open and honest conversations with the pharmacy owner about anything which could affect their ability to provide the full range of services that the pharmacy provides.

Unregistered staff

Unregistered pharmacy staff do not have the same responsibilities, as they are not regulated by the GPhC. But we expect them to meet our training requirements according to their role, to make sure they provide safe and effective care.

We know unregistered pharmacy staff work in a variety of roles including as dispensers, medicines counter assistants, delivery drivers and pharmacy managers. They may work full time, part time or occasionally, and their responsibilities may include:

- providing information and advice on symptoms and products
- selling and supplying medicines
- receiving and collecting prescriptions, including assembling and dispensing prescribed items
- delivering medicines
- ordering, receiving and storing medicines and pharmacy stock
- leading and managing teams

Unregistered pharmacy staff are accountable firstly to their employer, who will generally be the pharmacy owner or an NHS trust or health board.

Unregistered staff should, within the resources provided, keep their knowledge and skills up-to-date. They should only carry out roles for which they have the necessary skills and competency, or, if they are in training for that role, with appropriate oversight from a qualified member of the pharmacy team.

This guidance is set out under Principle 2 of the standards for registered pharmacies.

Principle 2: Staff are empowered and competent to safeguard the health, safety and wellbeing of patients and the public

The staff you employ and the people you work with are key to the safe and effective practice of pharmacy. Staff members, and anyone involved in providing pharmacy services, must be competent and empowered to safeguard the health, safety and wellbeing of patients and the public in all that they do.

Standards

2.1 There are enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided

2.2 Staff have the appropriate skills, qualifications and competence for their role and the tasks they carry out, or are working under the supervision of another person while they are in training

2.3 Staff can comply with their own professional and legal obligations and are empowered to exercise their professional judgement in the interests of patients and the public

2.4 There is a culture of openness, honesty and learning

2.5 Staff are empowered to provide feedback and raise concerns about meeting these standards and other aspects of pharmacy services

2.6 Incentives or targets do not compromise the health, safety or wellbeing of patients and the public, or the professional judgement of staff.

1. Setting staffing levels and responding to concerns about patient safety

The number of staff and the skill mix needed to provide safe and effective pharmacy services will vary significantly between pharmacies, depending on the context in which each pharmacy is operating. As the pharmacy owner you should consider the individual context of each pharmacy, including:

- the volumes of dispensing
- the sale or supply of medicines over the counter
- how and where medicines are supplied to patients (for example 'hub and spoke' or internet pharmacies)
- the changing demands throughout the day
- the population served by the pharmacy, including vulnerable patients
- changes in the number of patients and their individual needs
- the use of technology, including robotics
- the range of different services provided
- the different sets of skills, knowledge and experience within the team
- the ongoing learning and development of the pharmacy team
- previous incidents and errors, and the reasons for them
- feedback from patients and members of the public.

This means you have to take a tailored approach to staffing levels; one that is flexible and makes sure people receive safe and effective care from every registered pharmacy.

As a pharmacy owner you should make sure:

- you carry out risk assessments that are specific to the pharmacy and the team working there
- the way you manage risks, includes procedures to make judgements about the appropriate number of staff and the skill mix
- you develop, working with the responsible pharmacist, a staffing plan which takes account of the individual context of the pharmacy
- the responsible pharmacist and all members of the pharmacy team are aware of the staffing plan for their individual pharmacy
- each registered pharmacy has a contingency plan for short- and long-term staff absence, whether planned or unplanned
- you actively review the actual number of staff in the pharmacy who are competent and trained to deliver the pharmacy services provided, against the staffing plan – in line with changing services, workload, feedback and concerns

- all members of the pharmacy team know who they should contact within their individual pharmacy or wider organisation to raise concerns, without fear. This includes when staffing plans are not effective, and staffing levels and the skill mix may no longer be appropriate
- everyone in the pharmacy team has the knowledge and confidence to raise concerns about the quality of pharmacy services and, in particular concerns, about patient safety
- if concerns have been raised, there are systems, evidence and records to show the steps taken to deal with the concerns, so patient safety is not compromised
- feedback is provided to the pharmacy team about concerns raised and how the concerns have been dealt with
- the reasons for any dispensing errors are assessed and appropriate remedial action taken to learn from these. This includes action to change the number or skill mix of the pharmacy team when necessary
- the pharmacy team record, review and learn from near misses, mistakes or incidents.

2. Leadership and management roles

Pharmacy owners must make sure that pharmacy professionals who work for them can meet their own professional and legal obligations, and are able to exercise their professional judgement in the interests of patients and the public.

Managers who have responsibility for leading and managing teams, and for co-ordinating many aspects of the day-to-day pharmacy operations, have an important role to play. Members of the board, people in leadership roles and managers have significant influence over the culture, practices and environment of the pharmacy. They also have a significant influence over how the safe and effective delivery of pharmacy services is maintained.

As a pharmacy owner you should make sure that those in leadership and management roles:

- understand the legal and regulatory framework they are working in and the responsibilities of the pharmacy owner
- are familiar with the standards for registered pharmacies and with this guidance
- are familiar with the standards for pharmacy professionals, and the supporting guidance that we publish
- understand that pharmacists and pharmacy technicians, as regulated pharmacy professionals, have professional responsibilities. These include making patient safety a priority and taking action to protect the wellbeing of patients and the public
- understand that pharmacy professionals are accountable to the GPhC for meeting the standards for pharmacy professionals
- make sure everyone in the pharmacy team knows and understands the procedures in place in the pharmacy, as well as their own duties and responsibilities and those of other members of the team
- make sure pharmacy professionals and unregistered members of staff are supported and empowered to handle challenging situations confidently and professionally, whether that means having the right conversations with managers or knowing when and how to raise a concern with the pharmacy owner
- understand how to manage appropriately any personal or organisational goals, incentives or targets without compromising the professional judgement of staff to deliver safe and effective care
- make sure people who use pharmacy services can easily see who staff are and the role they are carrying out.

3. Maintaining a person-centred environment

Having staff with the right knowledge and skills is one part of being able to provide safe and effective care. It is equally important for the pharmacy team to demonstrate the attitudes and behaviours that people who use pharmacy services expect to see. It is often behaviours and interpersonal skills – such as effective communication and professionalism – that can put patients at ease and make the difference to the care they receive.

As a pharmacy owner you should make sure everyone in the pharmacy team:

- provides compassionate care which is adapted to meet the needs of each person
- can adjust their style of communication, and recognise and reduce barriers to effective communication
- is aware of safeguarding procedures and can identify people who may be vulnerable
- helps individuals to make informed choices about their health and wellbeing
- works with other healthcare providers to provide 'joined-up' care and demonstrate effective team working
- is encouraged to ask patients appropriate questions to make sure they are giving suitable advice
- recognises and values diversity, and respects cultural differences – making sure that every person is treated fairly whatever their values and beliefs
- understands the principles of privacy and confidentiality[3] and puts these into practice
- takes steps to maintain privacy and confidentiality and to ensure discussions are not overheard by people not involved in the person's care
- understands their responsibilities for keeping records up to date, complete and accurate, and for storing information in line with established procedures.

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[3]https://ico.org.uk/for-organisations/guide-to-the-general-data-protection-regulation-gdpr/ Overview of the General Data Protection Regulation (GDPR)

4. Knowledge, skills and competence

The GPhC sets the minimum training requirements for pharmacy staff. However, we also know that education and training does not stand still, and must reflect developments in medicines and technology and the diverse nature of pharmacy services. Pharmacy owners must make sure staff have the appropriate knowledge, skills and competence for their role and the tasks they carry out, or that they are working under the supervision of an appropriately trained person while they are in training.

Education and training requirements for such a diverse workforce should be flexible and proportionate to allow the pharmacy team to respond to changes in pharmacy practice.

4.1 Initial education and training requirements

As a pharmacy owner you should make sure:
- you understand the options for relevant training provision, so you can make decisions on what courses are appropriate for your staff. This may include speaking directly to course providers and pharmacy professionals about training needs
- a role-specific induction is carried out as soon as possible for all new members of the pharmacy team
- you recognise and address differences in competency requirements for specific practice settings and for the types of services being delivered in that setting
- you assess the competence of staff when they start in their role, and work in partnership with a pharmacy professional to make an informed decision about what further knowledge or training staff may need. This should include considering the staff member's previous education and training, their qualifications and their work experience
- initial training covers a common set of skills and abilities including professionalism, good communication skills, and effective working in multi-professional teams
- unregistered pharmacy staff who need education and training to meet the required competency level for their role are enrolled on an appropriate training programme within three months of starting in their role
- unregistered pharmacy staff who are involved in dispensing and supplying medicines are:
    - competent to a level equivalent to the relevant knowledge and skills of a nationally recognised Level 2 qualification in England and Wales, or a Level 5 qualification in Scotland, or

– training towards this and working under the supervision of a qualified member of staff
- you keep complete and accurate records of training for all staff, which are accessible to those who need them.

4.2 Learning and development

To maintain a competent and empowered pharmacy team, it is vital that learning and development continues beyond initial education and training. Pharmacy owners, working with pharmacy professionals, should:
- encourage and enable all staff – particularly those still in training – to reflect on their performance, knowledge and skills, and to identify learning and development needs, and
- support them in meeting those needs, to enable them to carry out their role.

Staff should be empowered to use their judgement, make decisions where appropriate and be proactive in the interests of patients and the public.

As a pharmacy owner you should make sure:

- you fully consider the learning and development needs of your team
- pharmacy staff work within the limits of their competence and refer to other, more appropriate, staff when they need to
- everyone in the pharmacy team, with the help of other members of the team, within the resources provided, keeps their knowledge and skills up to date
- managers have the competence, skills and experience needed to carry out their role
- essential elements of training are identified for each role within the team, and these are actively reviewed and reassessed in response to changing needs and circumstances, and any changes are made in a timely manner
- you can demonstrate that learning and development is taking place
- individual and team development plans are in place to make sure pharmacy staff are not carrying out roles they have not been trained for
- you take a tailored approach to learning and development which is continued throughout individuals' employment to make sure the knowledge and skills of pharmacy staff remain up to date
  you have considered whether you can make protected time available for learning and development.

Consultation on guidance to ensure a safe and effective pharmacy team

Analysis of the effects on equality

EA completed by:			
Signed:		**Date:**	
Name:	Carole Green, Policy Manager	**Date:**	

EA approved by:			
Signed:		**Date:**	
Name:	Priya Warner, Head of Policy & Standards	**Date:**	

1. Aims and purpose of the project/policy
1.1 This paper analyses the equality and diversity implications of proposed new guidance for pharmacy owners regarding a safe and effective pharmacy team in order to give effect to the Public-Sector Equality Duty under section 149 of the Equality Act 2010. This requires the GPhC to have due regard to each of the statutory objectives, including the need to: a. eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;   b. advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;

c. foster good relations between persons who share a relevant protected characteristic and persons who do not share it.

1.2 Conducting an analysis of the equality and diversity implications of our proposals also helps to ensure that we are not acting in a way that is incompatible with a Convention right[1].

1.3 Assessing the equality, diversity and inclusion impact of our policy development work is about being proactive in facilitating opportunities for people with the widest possible range of experiences and perspectives to engage with and influence our values, our culture, our strategy and the work we do. We aim to take an inclusive approach to working with users of pharmacy services, registrants, stakeholders and people affected in any way by our policy decisions.

1.4 This EIA includes an overview of the work we have completed to inform our understanding of the equality and diversity dimensions of the proposed guidance; and, to consider the potential impact on these groups. This has been informed by our quantitative and qualitative analysis of responses to the consultation; the available data and/or evidence relating to and, our engagement with a wide variety of stakeholders.

1.5 We have updated the analysis throughout the different stages of the policy development process, including pre-consultation, during the consultation and engagement period and post-consultation.

1.6 The analysis is intended to assist Council in considering whether the registered pharmacies guidance: a safe and effective pharmacy team should be approved and/or subject to further amendment before introduction.

1.7 At all stages of the process, we have considered how best to engage with equality groups, and equality and diversity issues have informed our policy development plans from the outset. We have sought to identify and mitigate any adverse impact on groups of people with a protected characteristic, including pharmacy owners and pharmacy professionals, unregistered pharmacy staff and people using pharmacy services. We have also considered how the proposed changes can help make a positive impact on these groups.

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

Policy context

1.9 In 2010 the GPhC adopted the RPSGB's minimum training requirements for unregistered pharmacy staff and took over the accreditation of dispensing assistant (DA) and medicines counter assistant (MCA) courses. The terms 'medicines counter assistant' and 'dispensing assistant' do not represent precise roles. 'Dispensing assistant' in particular is an umbrella term for a variety of roles supplying medicines to the public.

1.10 Unregistered pharmacy staff refers to staff within the pharmacy team who are not registered with us but are involved in pharmacy services at or from a registered pharmacy. This includes dispensers and medicines counter assistants, as well as unregistered pharmacy managers.

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[1] The Human Rights Act 1998, Section 6

1.11 The GPhC minimum training requirements policy, which was formally approved by Council in 2011, places a responsibility on individual pharmacists to make sure staff working in a pharmacy are competent for the role they undertake.

1.12 There has been a range of work undertaken over the last five years to enhance our understanding of issues within the pharmacy team.

1.13 As part of our work to review the initial education and training standards for pharmacists, pharmacy technicians and independent prescribers, we thought it was right to look at the education and training of unregistered pharmacy staff.

1.14 While we do not regulate unregistered pharmacy staff, we know they are often the first point of contact with patients and the public and have an important contribution to make within the pharmacy team.

1.15 Following a range of consultations and evaluation exercises over the last two years which provided useful background and insight into the role, functions and accountability for unregistered pharmacy staff working in registered pharmacies, we proposed to update the regulatory framework for unregistered pharmacy staff including new guidance for pharmacy owners[2].

1.16 We consulted on our proposed regulatory framework and guidance for the safe and effective pharmacy team[3] between 20 July 2017 and 11 October 2017. We then coded and analysed the consultation responses and incorporated the comments in our revised guidance.

1.17 Our Council considered the analysis, in March 2018, and will consider the revised guidance in May 2018 and if Council approves it, the new guidance for pharmacy owners will come into effect later in 2018.

1.18 If approved the proposals, which are set out in the consultation analysis report in detail, will make pharmacy owners accountable for making sure unregistered staff are competent for their role. The guidance for pharmacy owners would include the current policy on minimum training requirements for dispensing/pharmacy assistants and medicines counter assistants.

1.19 Once we have finalised the guidance, we will promote the draft guidance to pharmacy owners, and the pharmacy team via a range of communication channels, as well as with course providers and awarding bodies to make sure they are aware of our current position.

1.20 In carrying out this analysis, we have considered the potential equality and diversity implications of the proposed regulatory framework and the new supporting guidance.

2. Review of available information and/or data

Developing our evidence-base

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[2] Developing an updated regulatory framework for unregistered pharmacy staff March 2017

[3] Consultation on guidance to ensure a safe and effective pharmacy team July 2017

2.1 We have carried out a systematic and evidence-based approach to our policy development, including our assessment and understanding 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 our policy development, as there are gaps in the data we have regarding unregistered staff. As we do not regulate unregistered staff we do not hold the available data in relation to equality and diversity, so our information is limited.

2.3 As part of the consultation a short questionnaire (based on the same questions as the online survey) was sent to stakeholders to promote the consultation to unregistered pharmacy staff.

2.4 We have used the data we gathered through our online survey in response to the equality question and the data from our equality monitoring from the short survey, as well as other information, including the equality analysis published in relation to the Department of Education's Apprenticeship funding from May 2017.

2.5 Our Communications team looked at ways to engage with unregistered pharmacy staff and considered different engagement events. The practicalities of identifying and contacting unregistered staff and carrying these out was challenging and did not proceed.

2.6 At the Pharmacy Show we asked unregistered pharmacy staff to complete the short survey on our iPad.

Legal framework

2.7 The Pharmacy Order 2010 provides powers in relation to publication of guidance and our powers in relation to education and training and acquisition of experience.

2.8 In developing the guidance, we gave due regard to our statutory objectives under Section 149 of the Equality Act 2010 and we believe that the proposals align with our over-arching objective which is the protection of the public[4].

2.9 Overall, we believe that the proposals are fair and justified as good and beneficial for both the people who receive pharmacy services and safe and effective pharmacy staff, as the pharmacy owner will be responsible for meeting the guidance.

3. Screening for relevance to equality and diversity issues	
Does this project/policy have any relevance to (delete as appropriate)	
Age	Yes
Disability	Yes
Gender reassignment	No

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[4] The Pharmacy Order 2010, Article 6(1)

Marriage and civil partnership	No
Pregnancy and maternity	Yes
Race	Yes
Religion or belief	No
Sex	Yes
Sexual orientation	No
Welsh language scheme	Yes
Full EIA	**Yes**

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 marked Yes/No to categories in the screening table where we believe there may be an impact on with those protected characteristics.

4.3 If approved, the proposed guidance will apply to all pharmacy owners and the whole pharmacy team.

4.4 The potential impact of these changes, from an equality and diversity perspective, has been included in the impact assessment in Section 8 below.

5. Consultation / Involvement

5.1 We used a wide range of communication activities to maximise participation in the consultation across a diverse range of stakeholder groups, as well as general and targeted engagement approaches to reach all potential audiences. Below is a summary of our extensive consultation and engagement activity:

   a. Feedback from *Tomorrow's pharmacy team* [5] discussion was used to inform and help develop the guidance.
   b. Consultation launched via a press release on 20 July 2017 [6]
   c. Emails to all registrants and stakeholders with a link to the online survey, concurrent with the launch (potential respondents were invited to respond via an online survey, by email or by post. Hard copy, large font and other language versions of the document were available on request
   d. Articles in the GPhC online publication 'Regulate'
   e. Provision of a content 'tool kit' with FAQs, pre-written news stories, and twitter posts to help stakeholders promote the consultation through their networks

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[5] Tomorrow's pharmacy team (GPhC 2014.)

[6] Consultation on guidance to ensure a safe and effective pharmacy team (GPhC July 2017)

f. Follow up emails to registrants and stakeholders on 2 October 2017 with updated FAQs. The FAQs were simultaneously put on our website.
g. Short questionnaire (based on the same questions as the online survey) sent to stakeholders on 20 September, to promote the consultation to unregistered pharmacy staff
h. Members of staff on hand to answer any questions throughout the consultation process
i. The consultation was promoted at the RPS Conference and the Pharmacy Show, with two sessions led by the CEO.
j. At the Pharmacy Show we asked unregistered pharmacy staff to complete the short survey on our iPad.
k. Attendance at the Inspectors meeting (September 21, 2017) to understand their views on the practical implications of the proposals
l. Multiple trade and national press articles relating to the consultation

Patient focus groups

5.2 We held focus groups in London, Cardiff and Glasgow, which allowed us to discuss the consultation questions in depth with patients and the public. Feedback gathered through these groups, who were broadly representative of the British population in terms of age, gender and ethnic background, is not intended to be seen as representing the views of all patients and members of the public, but rather a snap shot of a variety of views to inform our work.

Pharmacy focus groups and roundtables

5.3 We held three roundtable meetings in London. One roundtable was attended by pharmacy stakeholders including 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. The other roundtables were attended by training providers and awarding bodies.

5.4 We are aware that unregistered pharmacy staff are not regulated by the GPhC and so are difficult to reach. We asked employers and other groups when they attended our roundtables and the LPC meetings to inform their unregistered staff of the consultation and to encourage their staff to complete the survey.

6. Date and method of consultation

6.1 The consultation on the safe and effective pharmacy team was open for 12 weeks (20 July 2017- 11 October 2017). As part of the consultation survey, we have included a question about equality and diversity (Question 11: "Do you think the proposal might have an impact on certain individuals or groups who share any of the protected characteristics") to ensure that we captured any issues that respondents wish to raise. We analysed the responses provided by stakeholders to question 11 of the survey. They are integrated in section 8 of the EIA.

6.2 In total we received written responses from 123 organisations and 708 individuals in the survey. From these 831 responses to the online survey: 818 answered this question.

- 682 respondents (83.4 per cent) did not think there was anything in the framework or proposed guidance that would have an impact on certain individuals or groups who share any of the protected characteristics
- 136 respondents (16.6 per cent) felt that our proposals would have an impact on certain individuals or groups who share any of the protected characteristics
- 14 respondents did not comment on that question
- 92 respondents provided further comment

6.3   We analysed the responses provided by stakeholders to this survey. They are integrated in section 8 of the EIA.

6.4   As part of the consultation survey, we also included a question about the impact of our proposals on pharmacy owners, pharmacy professionals, unregistered pharmacy staff and people using pharmacy services.

6.5   We have looked at the views where our proposals are thought to have an impact and how to mitigate this where possible.

6.6   In total, we received written responses from 78 individuals to the short survey.
- 41 respondents (55 per cent) were dispensing assistants
- 5 respondents (6.6 per cent) were medicines counter assistants
- 5 respondents (6.7 per cent) were non-registrant pharmacy managers
- 22 respondents (30 per cent) were registrants and
- 2 respondents were a trainee dispenser and a trainee technician

36 of the respondents completed the short survey equality monitoring form. However, we are unable to say who from those who completed the equality monitoring form were unregistered staff.

6.7   As we had limited data from the short survey equality monitoring form, we cannot extrapolate these findings further to provide any meaningful insight into whether unregistered staff would identify with certain protected characteristics.

6.8   Please refer to our analysis of consultation responses for further detail on the methodology.

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

7.1   Please refer to our analysis of consultation responses for details of the outcomes.[7]

7.2   All issues relating to equality and diversity identified through the engagement and consultation process have been set out in detail in Section 8 below.

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8. **Full impact assessment**

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[7] A safe and effective pharmacy team: Consultation report

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.

8.1 Different age groups will have different training needs, methods of learning and concerns. As part of the feedback received, we have sought to assess the impact of our proposals on people of different ages.

8.2 In our current minimum training requirements for dispensing /pharmacy assistants and medicines counter assistants[8] there is an exemption for assistants who qualified prior to January 2005 and who were declared competent under the grand parenting clause to meet the knowledge and understanding associated with one or more units of the S/NVQ level 2 Pharmacy Services. Exemption applies only to those areas of work in which the supervising pharmacist declared the assistant competent.

8.3 Quite a few respondents in the main survey commented that our proposals would affect these members of staff who were 'grand parented' and who may be required to undergo further training. There were differing opinions expressed regarding the level of knowledge of 'grand parented' staff. Some respondents expressed the view that these members of staff may have worked for years in their roles without the level of training, do not consider they need further training, are resistant to change, would struggle with having to prove their competency and may be reluctant to do further training and/or not been given adequate training, so may not be up to date.

8.4 It was however also commented that these members of staff may be competent and knowledgeable. One respondent commented that they already have accreditation and that they would now need to re train even though they have been doing their job for many years.

8.5 Other respondents commented that our proposals may cause grand parented staff to leave the sector as experienced staff may not agree to sign up to training courses or because they thought their training was worth nothing.

8.6 In our consultation it was also pointed out that some older staff and part time staff cannot access university learning mode as they have other responsibilities after work or not want to take on extra commitments. They felt it may be important to make this as in-house training in company time.

8.7 It is important that the pharmacy team provide safe and effective care. We made it clear that we have adopted an outcome focussed approach to training, and it is the pharmacy owner that will be responsible for the training of staff to ensure they are competent and have the necessary skills for their roles.

8.8 We listened to the feedback in regards the proposal to include the minimum training requirement as part of the guidance and to have no exemptions. We propose not to implement this change at this time. The minimum training requirement will currently remain with the current exemptions.

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[8] Policy on minimum training requirements for dispensing /pharmacy assistants and medicines counter assistants[8]
https://www.pharmacyregulation.org/sites/default/files/minimum_training_requirements_da_mca_sep_2011.pdf

8.9 We propose that the education related work for unregistered staff is taken forwards as part of the education development work. This will ensure that the principles and approach to all of our education and training, and quality in education is aligned.

Disability – consider environmental, social and attitudinal barriers

8.10 As we know people with disabilities face many barriers in accessing employment and training provision. As part of the feedback we have sought to assess the impact of our proposals on people with disabilities.

8.11 Several respondents considered that our proposals would affect unregistered staff with learning disabilities, autism and dyslexia. In addition, staff with ADHD would find it very difficult to complete the NVQ2 course.

8.12 A few respondents commented that those who struggle with formal learning are often not impaired when it comes to practical learning.

8.13 One respondent commented that that the training they had assisted staff in completing does not seem to accommodate dyslexic staff members.

8.14 Another respondent felt that with courses costing £500 there would be more competition for work and that those with learning disabilities would be unfairly disadvantaged.

8.15 Another person felt that pharmacists may indirectly discriminate against staff that may have special learning requirements or students requiring reasonable adjustments. It was pointed out that currently the NPA follows a standard operating procedure that uses the GPhC accredited courses as the standard to determine how the 'reasonable adjustments' are to be set out. The respondent continued that in the absence of training courses no longer being accredited, variance could be introduced.

8.16 The current courses are flexible and allow course developers and providers to be responsive to the needs of pharmacy owners and unregistered staff.

8.17 We listened to the feedback regarding the minimum training requirements and we propose not to implement this change at this time. We will continue our programme of approval of the current courses, which also includes equivalent courses

8.18 We propose that the education related work for unregistered staff is taken forwards as part of the education development work. This will ensure that the principles and approach to all of our education and training, and quality in education is aligned.

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.

8.19 Through the equality and diversity question in the survey, we did not hear of any issues relating to gender reassignment. This means we cannot fully assess whether our proposals are likely to have differing impacts on unregistered staff in relation to gender reassignment.

Marriage or Civil Partnership – consider impact on married people or people in a civil partnership, young or old

8.20 Through the equality and diversity question in the survey, we did not hear of any issues relating to marriage or civil partnerships. This means we cannot fully assess whether our proposals are likely to have differing impacts on unregistered staff in relation to marriage or civil partnership.

Pregnancy or maternity – consider impact on pregnant women and those on maternity leave

8.21 We have addressed the potential impacts in relation to pregnancy and maternity in the context of the impact on sex in the section below.

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

8.18 In the consultation responses it was also highlighted as an advantage of employing staff locally, as members of the pharmacy team will have connections with the community they serve, so that the role and qualifications needed should be flexible and adaptable to local needs.

8.19 It was pointed out that for members of the pharmacy team where English is not the first language, these groups would be disadvantaged by our proposals.

8.20 One organisation commented that not all members of the pharmacy team share the language and 'client sensitive' communication skills needed which are highly valued by those with protected characteristics. It was felt that these members of the pharmacy team that do, have a responsibility to ensure that advice and support isn't lost in translation. They commented that addressing the diverse needs of a local community shouldn't be an after-thought but integrated into plans to achieve and maintain a minimum pharmacy service quality standard. They pointed out that as pharmacy staff are recruited from a local community they bring a good understanding of cultural sensitivity with them and sometimes the pharmacy is the only local health service locally which meets the needs of groups who share protected characteristics.

8.21 Unregistered staff however are supervised by pharmacy professionals who have the professional responsibility to support their staff in their learning and training and demonstrate team working and effective communication. This should help mitigate any negative impact of our proposals.

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

8.22 We heard from a range of respondents, some identifying with a religion and those having no religion, but none raised any concerns.

8.23 We are aware that with limited data we cannot fully assess whether our proposals are likely to have differing impacts on unregistered staff in relation to different religions or beliefs or none.

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

8.24 It was highlighted that unregistered staff working part time, who are more likely to be from specific groups e.g. disabled, older, or women would be impacted by our proposals. It was felt that women who work part time would be impacted by the proposal to be enrolled on a course within three months of starting. It was considered that this may not be enough time to assess their training requirements before enrolment onto a course.

8.25 Also, another respondent commented that women contemplating pregnancy, or those on maternity leave would be impacted by our proposals.

8.26 Where the number of unregistered staff is predominantly women, there is likely to be more instances of pregnancy and maternity leave.

8.27 We listened to feedback and will not be introducing the changes to the minimum training requirements and we propose not to implement this change at this time. We will continue our programme of approval of the current courses, which also includes equivalent courses

8.28 We propose that the education related work for unregistered staff is taken forwards as part of the education development work. This will ensure that the principles and approach to all of our education and training, and quality in education is aligned.

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

8.22 Through the equality and diversity question in the survey, we did not hear of any issues relating to sexual orientation. This means we cannot fully assess whether our proposals are likely to have differing impacts on unregistered staff in relation to sexual orientation.

Other diversity and equalities related issues

8.23 We have also considered the following equalities related issues:

Workplace pressures and staffing levels

8.29 Some respondents highlighted the potential impact of the changes on already overworked and overstressed pharmacists. They though the added pressure of an even more onerous system could trigger mental instability, depression or anxiety in pharmacy professionals.

8.30 Many respondents wanted to see minimum staffing levels in the guidance, based on the volume of prescriptions or the turnover of the pharmacy. They said this would ensure patient safety and alleviate the pressure and stress levels currently experienced by pharmacy staff.

8.31 We believe that the right staffing levels are best done by the people responsible for managing the pharmacy. We have listened to the feedback and have strengthened what the guidance says about staffing levels, and made this a separate section within the guidance, to mitigate against this.

8.32 We listened to feedback and will not be introducing the changes to the minimum training requirements and we propose not to implement this change at this time. We will continue our programme of approval of the current courses, which also includes equivalent courses.

8.33 We propose that the education related work for unregistered staff is taken forwards as part of the education development work. This will ensure that the principles and approach to all of our education and training, and quality in education is aligned.

8.34 The GPhC works closely with organisations including Pharmacist Support, leadership bodies and employers and individuals to consider what can be done do to help people affected by workplace pressures including mental health issues.

Access to services

8.24 One organisation commented that for a person with Parkinson's having access to a safe and effective pharmacy team is a crucial part of managing the condition. From the perspective of a people with Parkinson's the skills found in the community pharmacy team have the potential to add great value to their care.

Different working environments

8.25 The training needs for community and hospital staff can be very different.

8.26 Our research and consultation responses to the initial education and training standards for pharmacy technicians underlined differences in training in community and hospital pharmacies. For instance, hospital trainees were more likely to have two to four hours of protected study time per week, whereas community trainees more likely to have less than two[9]. Another example of this is that hospital trainees rotate in different departments across the hospital estate, so that they cover different elements of their competence skills[10]. This is not the case for community pharmacy trainees.

8.27 A few respondents felt that hospital pharmacies and other environments were not clearly included in the guidance.

8.28 To mitigate against this, we have said in the guidance that it is intended to be helpful for other organisations who employ pharmacy professionals or provide pharmacy services across a range of settings, for example hospitals and industry, although we do not regulate all these settings. It is intended to allow flexibility to account for the different locations, modes of delivery and roles of trainees.

Different methods of learning and ability

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[9] Survey of 2014-2015 pre-registration pharmacy technician training and The quality of pharmacy technician education and training: A report to the General Pharmaceutical Council 2014
[10] The quality of pharmacy technician education and training: A report to the General Pharmaceutical Council 2014

8.29   Quite a few respondents commented that unregistered staff may struggle with different aspects of any training programme. These included:

- people may need longer to complete as there are some groups who would not manage formal training, and owners should consider this;
- currently being able to nurture staff and build their confidence and academic ability, which all takes substantial time, is not recognised in proposals;
- some of the untrained staff have excellent people skills compared with trained ones who at times are very structured in their communication skills;
- with a more difficult and intense NVQ2 qualification would make it much harder for people with protected characteristics to engage;
- people that are not able to read and learn through books but are able to learn via practical work will be disadvantaged;
- some of their most competent staff would not be able to pass this training;
- individuals respond to different means of receiving information and training.
- some, who struggled with language issues at some levels were put off from entering the formal education system. Others have very good people skills but like to learn in different ways and to remove these options by being prescriptive would further disadvantage such individuals.

8.30 One respondent felt that the current GPhC accredited programmes were user friendly and at the right level of requirement and considered that most people should have no problem passing the course. However, they felt the full NVQ course was generally a lot tougher and very time consuming. Those who are slow learners or academically less bright may find it very difficult to get through the course.

8.31 One respondent commented that some staff, having to sit a complicated and unnecessary training course would cause them stress. They felt the current training program suited their community pharmacy well, but that employers did not put staff through the current existing programmes.

8.32 Another respondent highlighted that the guidance is not clear on modes of delivery for the training/assessment and adjustments that might be needed for individual learners. They considered the guidance leaves 'protected' study time to the owner's discretion. This could lead to variability across employers which would be unfair to the learners.

8.33 We listened to the feedback regarding different methods of learning and ability and we propose not to implement the change to the minimum training requirements. We will continue our programme of approval of the current courses, which also includes equivalent courses. This flexibility allows unregistered staff member to learn in a variety of different ways.

8.48 We propose that the education related work for unregistered staff is taken forwards as part of the education development work. This will ensure that the principles and approach to all of our education and training, and quality in education is aligned.

Marginalised groups and poorer communities

8.34 One organisation highlighted that 'cultural' and age sensitivities can act as significant barriers to patients, especially when they have more than one protected characteristic and strict confidentiality can be very important for some clients e.g. some poor communities have strongly held if misguided cultural beliefs about mental health, sexuality and the value of 'traditional custom and practice' which

local pharmacies have a responsibility to react to in a sensitive way but which puts the needs of the patient to receive safe and appropriate healthcare above all other considerations.

8.35 One respondent commented that populations who live in poorer communities in the UK, where people are less aware of their rights, can be easily manipulated and rely on good quality pharmacy services.

8.36 It was felt there was a positive impact in terms of overall staff awareness and skills to support these groups in terms of their diverse needs and compassionate care, but a negative impact where pharmacy owners decide to restrict services that would otherwise benefit such patients e.g., delivery services, nomad systems rather than incur the additional training and associated costs. This may mean that some pharmacy owners might not send their staff on additional training.

8.37 Our guidance makes it clear that pharmacy owners should consider the needs of patients and people who use pharmacy services, and make sure their staff undertake the necessary training appropriate to their roles, which should mitigate any negative effects.

Apprenticeships

8.38 Apprenticeships are at the heart of the Government's drive to give people of all ages the skills that employers need to grow and compete. They want to make apprenticeships as accessible as possible, to all people, from all backgrounds. In December 2015, the Government published English Apprenticeships: Our 2020 Vision, which outlined the Government's plans to increase the quality and quantity of apprenticeships.

8.39 In introducing the new apprenticeships levy, the Department for Education (DE) published its equality analysis.[11] They have Individualised Learner Record (ILR) data on the status quo only available for age, disability, gender and ethnicity.

8.40 They have carried out an impact assessment and believe that the impacts on protected groups are broadly neutral.

Scotland

8.41 One organisation commented that the ability to complete many of the currently accredited courses remotely and in a condensed time frame is highly valued in Scotland.

8.42 Another organisation commented that pharmacy undergraduates working in Scotland in community pharmacy or hospital over the summer to gain experience could be impacted by our proposals. It was felt that pharmacy owners would have to consider whether to continue to take on undergraduate students. They thought that pharmacy employers would not be able to assess students as potential employees after graduation and students would not be able to gain experience to determine which sector of pharmacy they wanted to work in before qualifying.

8.43 We will continue to work with Scottish stakeholders to ensure they are aware of our proposals.

Wales

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[11] **Information from the equality analysis: Apprenticeships funding policy from May 2017**

8.44   We have not identified any specific issues relating to Wales apart from ensuring our guidance is available in the Welsh language.

10. Welsh Language Scheme
10.1 A Welsh version of our guidance and consultation document has been provided. This ensured that Welsh speaking stakeholders had the opportunity to provide input.
10.2 We will also provide a Welsh version of the finalised guidance.

11. Monitoring
How will the implementation of the proposal be monitored and by whom?
11.1 This analysis is intended to assist Council in considering whether the changes to the framework and guidance should be approved and/or subject to further amendment before introduction.
11.2 Once the new guidance has been finalised, we will continue to engage with awarding bodies and course providers on the implementation of our proposals.
11.3 We will continue to consider how feedback is incorporated into evidence gathering and ensure we have appropriate mechanisms in place to monitor any other equality concerns that emerge and how we will mitigate against them.
11.4 We will continue to assess through our inspections whether there is a sufficient number of staff to ensure a safe and effective pharmacy team.
How will the results of monitoring be used to develop this proposal and its practices?
11.4 The results from the consultation have informed the draft guidance.
11.5 The issues identified through this analysis will be taken into account when deciding whether further changes should be made to the framework and guidance prior to implementation.
What is the timetable for monitoring, with dates?
11.6 The supporting guidance will be reviewed, as and when appropriate or when there are changes to our standards and the inspection decision making framework.