

Council meeting

12 April 2018

13:30 to 15:15 **approx.**

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

Public business

1. Attendance and introductory remarks	Nigel Clarke
2. Declarations of interest <i>Public items</i>	All
3. Minutes of last meeting <i>Public session on 08 March 2018</i>	Nigel Clarke
4. Workshop summary – 8 March 2018	Nigel Clarke
5. Actions and matters arising	Nigel Clarke
6. Consultation on developing our approach to regulating registered pharmacies For approval	<i>18.04.C.01</i> Claire Bryce-Smith
7. Reviewing our publication and disclosure policy For noting	<i>18.04.C.02</i> Priya Warner
8. Safe and effective pharmacy teams For noting	<i>18.04.C.03</i> Mark Voce
9. Any other public business	Nigel Clarke

Confidential business

10. Declarations of interest*Confidential items*

All

11. Minutes of last meeting*Confidential session on 8 March 2018*

Nigel Clarke

12. Confidential actions and matters arising

Nigel Clarke

13. Any other confidential businessNigel Clarke

Date of next meeting

Thursday, 10 May 2018

Minutes of the Council meeting held on Thursday 8 March 2018 at 25 Canada Square, London at 13:30

TO BE CONFIRMED 12 APRIL 2018

Minutes of the public session

Present

Nigel Clarke (Chair)
Mary Elford
Digby Emson
Mark Hammond
Joanne Kember
Alan Kershaw

Elizabeth Mailey
Evelyn McPhail
Arun Midha – until item 100
David Prince
Samantha Quaye
Jayne Salt

Apologies

Mohammed Hussain, Berwyn Owen

In attendance

Duncan Rudkin (Chief Executive and Registrar)
Megan Forbes (Deputy Chief Executive and Director of Corporate Resources)
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)
Helen Dalrymple (Council Secretary)
Ruth McGregor (Head of Finance and Procurement) – item 97
Priya Warner (Head of Policy and Standards) – item 98
Damian Day (Head of Education) – item 99

91. Attendance and introductory remarks

- 91.1. The Chair welcomed all present to the meeting. Apologies had been received from Mohammed Hussain and Berwyn Owen.

92. Declarations of interest

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

93. Minutes of the last meeting

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

94. Workshop summary – 8 February 2018

- 94.1. **Council noted the discussions from the workshop.**

95. Actions and matters arising

- 95.1. In response to action minute ref. 84.12 on the log, Duncan Rudkin (DR) reported that none of the pharmacies being investigated under the Medicines and Healthcare products Regulatory Agency (MHRA)'s investigation were overdue for inspection. It was emphasised that the inspection process was transparent and not designed to uncover criminality.
- 95.2. Minute ref. 84.16; Francesca Okosi (FO) said that information on the cost of cancelled hearings would be circulated to Council members in April.
- 95.3. DR clarified that the action ref. minute 58.2 would include work on drawing out information on different kinds of pharmacy practice and identifying any action that would be required. This would be referenced in the Annual Plan as it was fundamental to the organisation's work. It would also come up in the workshop on strategy that was being held for members later in the year.

96. Annual Plan 2018/19

- 96.1. Megan Forbes (MF) presented **18.03.C.01**. This paper set out the activities to be undertaken as part of year two of the Business Plan 2017/20. It sought to achieve a balance between ambition and realism. The paper set out themes and aimed to embed

new ways of working in these work streams alongside delivering on the organisation's regulatory responsibilities.

- 96.2. Summary plans would sit underneath each theme. These would include 'what success looks like' and milestones. The plans would be kept under review as there was some uncertainty ahead.
- 96.3. The insight and intelligence strategy was not fully reflected in the plan at the moment. The work to develop the strategy had been included but the costs of delivering it were not yet known.
- 96.4. Members said that they were generally content with the plan and that the balance was about right. They discussed regulatory risk – the work towards aligning with ISO 31000 would be included in the plan.
- 96.5. Council asked how progress against the plan would be measured. They said that proportionality had to be built in to the document. MF explained that this was the case in the three year business plan and was also mentioned in the foreword. The paper would be sense checked further on that.
- 96.6. The General Data Protection Regulation (GDPR) Act, that would come into force in May would have governance oversight via the Audit and Risk Committee.
- 96.7. There was some discussion on the term 'strategic' priorities with some members feeling that this could be better defined.
- 96.8. Members questioned having a strategic objective around insight and intelligence without having worked out what the budget required would be to fulfil it. MF explained that scoping work on the strategy had not yet begun. The organisation was being careful to only commit to delivering a strategy at this point – further objectives would be identified following that.
- 96.9. The reference to exiting the European Union in the introductory paragraph was queried. DR told members that the organisation may have to spend time on work that was less strategic depending on the consequences of Brexit. This would be separated out more clearly in the plan.
- 96.10. The Council asked that care be taken with word 'ensure' and suggested an audit of how the word was used throughout the plan to make sure that it was appropriate.
- 96.11. DR told members that the organisation needed to understand as best as they could what future pharmacy practice looked like and that this would be added to the plan under the data, information, intelligence and insight heading.
- 96.12. **The Council agreed the Annual Plan for 2018/19; year two of the Business Plan 2017/20.**

97. Budget 2018/19

- 97.1. MF presented **18.03.C.02**. This paper sought approval for the budget for 2018/19, proposing that improved services were funded from reserves and that fees were held at current levels for 2018/19.
- 97.2. The paper was being presented to members one month later than usual. This was due to there being no need for a consultation as fees were to be held at the same level, as well as the impact that the restructure had in December which meant that new teams had been set up.
- 97.3. MF extended her thanks to colleagues for the enormous amount of work that had gone into the budget.
- 97.4. The paper expected that expenditure would run to £2.6m over income. Council were asked to agree that this deficit could be taken from reserves. This budget should be seen as a 'holding' budget. Delivery for the next year would be possible but a longer term financial strategy was required. Work on this would be shared with Council in June of this year, following the next meeting of the Efficiency and Effectiveness Assurance and Advisory Group (EEAAG).
- 97.5. Digby Emson, Evelyn McPhail, Elizabeth Mailey, Jo Kember and Samantha Quaye declared an interest as registrant members.
- 97.6. The Chair of EEAAG told members that they had asked for the executive to demonstrate a clear understanding of reserves, fees and savings for the next couple of years. Having been assured of this, they were happy to move forward with this budget.
- 97.7. MF said that it was clear that the forward projections looked uncomfortable but urged Council to remember that these were based on the organisation doing nothing which would absolutely not be the case.
- 97.8. Members showed general support but were emphatic that the further developed financial strategy must come to Council in the summer.
- 97.9. There was an error on the appendices on register numbers. On table i) Budget by income and expenditure type 'average registrant numbers - pharmacist' should be 56,555 rather than 52,335.
- 97.10. Council discussed whether fees should be increased rather than using reserves. They agreed that balance should be sought in reducing the level of reserves before increasing fees that year, but that this may not be a suitable strategy for the long term. DR pointed out that were fees to be increased for any category in future years, it would better to phase in gradually than to present anyone with a sudden increase.

97.11. Members expressed their unease at approving a budget that did not show how break even would be achieved. They accepted that certain regulatory levers had not been pulled but wanted a sense of ambition for when they would be. It would be prudent to agree the budget only on the proviso that it would be reviewed and brought to the Council meeting in June.

97.12. **Council:**

- i. **noted and commented on the proposed budget and assumptions set out in appendix one**
- ii. **agreed the budget for 2018/19 subject to a re-forecast that would be brought to the Council meeting in June**
- iii. **agreed that fees would be unchanged for the financial year**
- iv. **agreed to the application of reserves as described in line with ensuring that reserves were held at above target level of four to six months of operating expenditure**
- v. **noted proposed steps to update the longer term financial and fees strategy**

98. Consultation report: Guidance for a safe and effective pharmacy team

98.1. Priya Warner (PW) presented **18.03.04**. This paper provided Council with a report on the feedback from the consultation relating to the guidance on ensuring a safe and effective pharmacy team.

98.2. Members drew attention to the apparent low numbers of pharmacy owners who had responded to the consultation as shown in table 13 of the consultation analysis. PW explained that categorisation could be problematic as pharmacy owners who were pharmacists may describe themselves as a pharmacist rather than an owner.

98.3. Mark Voce (MV) agreed that the timetable was tight but said that it was deliverable. PW said that the team had remained in communication with training providers throughout the consultation and that all were aware that the accreditation process for training non-registered staff remained in place.

98.4. Members heard that the consultation had brought up issues such as probation periods and decision frameworks that would need to be dealt with.

98.5. The Council welcomed the fact that more information would be coming to them about workplace pressures and staffing levels.

98.6. **Council noted:**

- i. **The analysis of responses to the consultation (appendix one) and that they would be published on the website; and**
- ii. **That the responses were currently being considered before finalised guidance would be brought to Council.**

99. Revised criteria for registration as a pharmacy technician in Great Britain

- 99.1. Damian Day (DD) presented 18.03.C.03, which sought to agree the revised criteria for registration as a pharmacy technician in Great Britain, bringing into effect changes agreed by Council in September 2017.
- 99.2. The Chair explained that a comprehensive list of questions had been received in advance and circulated just before the meeting. This was because it was felt that they would aid discussion on this item.
- 99.3. Members wanted to know whether the current qualifications would be re-accredited or quality assured over the transitional period. DD said that current courses would be discontinued only when the new ones, based on the GPhC's 2017 education and training standards, were introduced.
- 99.4. DD also clarified that pre-registration pharmacy technicians currently enrolled on courses would continue on them and those courses would still count towards registration.
- 99.5. Any new courses would be accredited using the current accreditation methodology as and when they were ready to be accredited.
- 99.6. Members asked about whether it would be possible to provide a pre-registration number for pharmacy technicians. DD explained that the pre-registration number for pharmacists is a by-product of the validation of trainees, tutors and training premises, for which a fee is levied. It would not be possible to apply the same process to pharmacy technicians.
- 99.7. It was however, important to collect reliable data on registrants and to have equivalent data sets for both pharmacists and pharmacy technicians. The GPhC was working with course providers on data gathering so that the information held about pre-registration pharmacy technicians was the same as that held for pharmacist students and trainees.
- 99.8. Council discussed the fact that there was little sight of the issue around skills that needed to be present from day one of training such as patient confidentiality. They said that they would value further discussion on this. DD agreed that this was important work and needed to be done. It would sit well within the quality assurance work stream.
- 99.9. Members discussed the criteria for sign off. The new standards were stronger on sign-off and accountability, they emphasised the importance of understanding responsibility and would be checked at accreditation. The pre-registration trainee pharmacy technician would have to be signed off by someone whom they were accountable to.

- 99.10. There would be different methods of sign-off, some on a 1:1 basis and some with more than one supervisor; the criteria were designed to allow flexibility when appropriate.
- 99.11. Members noted that the provision allowing pharmacists to register automatically as a pharmacy technician had been removed. Periods of pharmacist pre-registration training could count towards the two-year work requirement for pharmacy technician registration but only on a case by case basis.
- 99.12. **Council:**
- **agreed the revised criteria for registration as a pharmacy technician in Great Britain; and**
 - **noted the proposed date for the revised criteria to come into effect**

100. Revalidation and new myGPhC launch

- 100.1. MV presented paper **18.03.C.05**. This paper provided information and assurance to the Council about the launch of revalidation and the new myGPhC online service, specifically risks and mitigations relating to the technical system testing and the communications activities which would be carried out to deliver this work successfully.
- 100.2. Members who were on the revalidation advisory group commended the work to their colleagues describing it as detailed, thorough and sensitive. Some resources had been made available to other organisations to help with explaining the process to their members.
- 100.3. MV assured Council that the increased volume of work at key points for the contact centre was anticipated and being prepared for. Extra staff would be available and detailed briefings were held regularly with staff, building their expertise in advance.
- 100.4. The online system worked well across a variety of different operating systems and this would continue to be closely monitored.
- 100.5. **The Council noted and discussed the content of the paper.**

101. Any other public business

- 101.1. There being no further public business to discuss the meeting closed at 15:20

Date of the next meeting:

Thursday 12 April 2018



Meeting paper

Council on Thursday, 12 April 2018

Public business

Council Workshop Summary

Purpose

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

Recommendations

The Council is asked to note the discussions from the workshop

1. Introduction

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

2. Summary of the March workshop

- 2.1. Council heard some initial feedback from the workshops review. Work was ongoing and a report would be circulated amongst members in due course.

2.2. *Revalidation Q & A Session*

A session was held with members to provide them with the opportunity to feed back on the revalidation portal and to discuss anything about the new revalidation process in advance of its launch.

This was followed by a paper in the meeting that afternoon which summarised the risks and mitigations related to systems testing and communications activities around the launch.

2.3. *Raising concerns*

The Council were given a presentation and a discussion was held on work being done around members of the public and registrants raising concerns within and about pharmacy. A platform was being developed for the GPhC website which would signpost people to the relevant support they required, including instances where a matter was not for a regulator but would be better dealt with elsewhere.

The discussion held here would inform further work on the platform.

2.4. *Registered pharmacies consultation*

Members were reminded of previous work on the inspection of registered pharmacies and the outcomes of previous discussions. They were advised on and discussed the proposed structure and strategy of the consultation as well as the timelines that it would follow.

Members' comments would feed into the consultation which would come to the Council meeting in April.

Recommendations

Council is asked to note the discussions from the workshop

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General Pharmaceutical Council

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Tel 020 3713 8011

26 March 2018

Council actions log

Meeting date	Ref.	Action	Owner	Due date	Status	Comments/update
6 Jul 2017	31.6	Consultation on revised threshold criteria: A report on equality, diversity and inclusion in Fitness to Practise processes would be brought to Council in due course.	Claire Bryce-Smith	Sep 18	Open	This report will be commissioned externally and will go out to tender in Jan/Feb 18. It is anticipated that it will take at least three months to produce the report.
9 Nov 2017	58.2	Actions and matters arising: Council asked for a brief comparative table of GPhC and Care Quality Commission (CQC) powers regarding premises, owners and businesses.	Duncan Rudkin	Apr 18	Closed	This was circulated to members by email on the 4 April.
	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	June 18	Open	
8 Mar 2018	95.2	Information on the costs of cancelled hearings would be	Francesca Okosi	April 18	Open	

		circulated to Council members in April				
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Meeting paper

Council meeting on Thursday, 12 April 2018

Public business

Consultation on developing our approach to regulating registered pharmacies

Purpose

To discuss and consider a consultation document on developing our approach to regulating registered pharmacies, including the publication of reports from inspections of registered pharmacies.

Recommendations

The Council is asked to:

- I. agree for consultation our proposals on developing our approach to regulating registered pharmacies and introducing the publication of reports from inspections of registered pharmacies.
- II. agree to delegate the final approval of the consultation document to the Chair

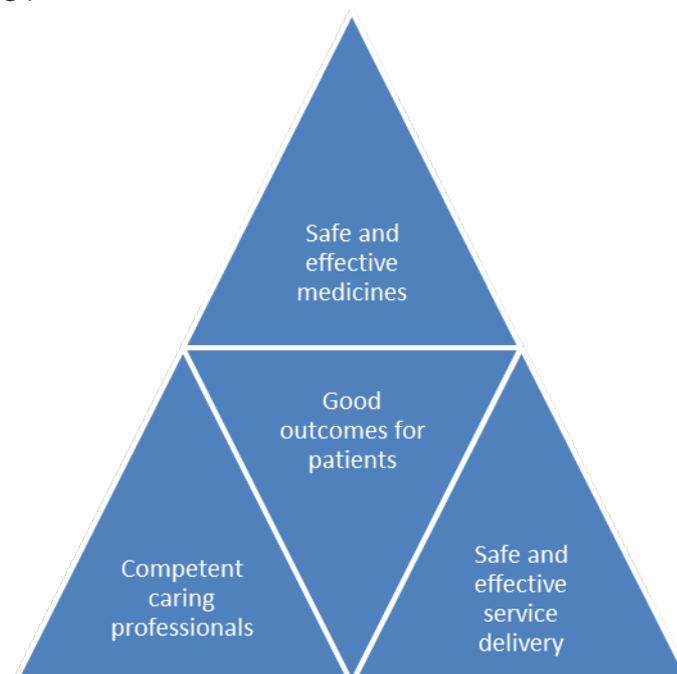
1. Introduction

- 1.1. We have, since 2012, been continuing to develop and implement our approach to regulation of registered pharmacies.
- 1.2. We now want to take the next step in developing our regulatory approach, in order to:
 - provide greater assurance to patients and the public and the pharmacy sector that registered pharmacies are meeting standards
 - further drive continuous improvement in the quality of services and care for the public
 - ensure we keep pace with ongoing developments in pharmacy.

- 1.3. We are now able to move forward with proposals, as we expect the Pharmacy (Premises Standards, Information Obligations etc) Order 2016 to be commenced shortly. This will make changes to the Pharmacy Order 2010, including giving the GPhC powers that enable us to publish the outcomes of inspections of registered pharmacies.
- 1.4. We plan to hold a 12-week public consultation to seek views on our proposals to further develop our approach to regulating and inspecting registered pharmacies and to publishing inspection reports.

2. Background

- 2.1. In 2012, we set out a new vision for the regulation of registered pharmacies in our consultation on *Modernising Pharmacy Regulation*¹. In this consultation, we set out the three key components that we believe are needed for patients and the public to receive safe, effective pharmacy services and care, which are represented below, in a ‘public protection triangle’:



¹ https://www.pharmacyregulation.org/sites/default/files/modernising_pharmacy_regulation.pdf

2.2. The Medicines and Healthcare products Regulatory Agency has the regulatory responsibility for ensuring medicines are safe and effective. We have the regulatory responsibility for the other two components in the triangle:

- Ensuring pharmacy professionals are competent, caring and practising to the right standards
- Ensuring the systems for managing and delivering pharmacy services are safe and effective.

2.3. This consultation focuses on how we will further develop our approach to the third component in the triangle; ensuring safe and effective service delivery.

2.4. The proposals in the consultation document have been informed by extensive previous work we have carried out. This includes:

- The introduction of new 'outcome focussed' standards for registered pharmacies in 2012
- The implementation of a new approach to inspection in 2013, which involves the whole pharmacy team and uses a 'show and tell' approach to help identify if standards are being met
- The publication of an update paper, *Modernising Pharmacy Regulation: from prototype to implementation*² in 2015, which highlighted the progress that had been made to modernise pharmacy regulation and plans for further work
- The publication of an external evaluation of our approach to regulating community pharmacies by ICF³ in 2015, which concluded that the GPhC's approach to regulating registered pharmacies is perceived to be working well overall, but also highlighted some areas that required further consideration, for example the terminology of ratings
- Ongoing engagement with stakeholders, including focus groups with patients and the public in 2017 to inform our inspection reports and approach to publication.

2.5. The Department of Health published a consultation document⁴ in February 2015 seeking views on the proposed draft of the Pharmacy (Premises Standards, Information Obligations etc) Order 2016. There was overwhelming support overall for the proposals, and the new legislation (the Pharmacy (Premises Standards, Information Obligations etc) Order) was agreed in 2016 and is due to come into effect shortly.

² https://www.pharmacyregulation.org/sites/default/files/modernising_pharmacy_regulation_-_from_prototype_to_full_implementation_february_2015.pdf

³ https://www.pharmacyregulation.org/sites/default/files/evaluating_the_gphcs_approach_to_regulating_community_pharmacies_-_final_report.pdf

⁴ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/403387/consultation_doc.pdf

- 2.6. We have reflected on what we have learnt from our current approach and from the consultation, engagement and evaluation summarised above. We now want to further improve our regulatory approach and take the next step to further drive continuous improvement by sharing our learning and insights from our inspections.

3. Key considerations: our strategic approach

- 3.1. Our strategic approach remains focused on assurance and improvement. This means providing assurance to patients and the public that the standards for registered pharmacies are being met in pharmacies across Great Britain and driving continuous improvement in the quality of services and care for the public.
- 3.2. The changes we are proposing strengthen both our ability to provide assurance to the public and to support pharmacy owners to continually improve the quality of services provided from registered pharmacies.
- 3.3. Our approach to regulating pharmacies must be flexible and agile, so we can respond effectively to the changing needs of patients and the public and to changes in how pharmacy services are delivered. It is clear that a 'one-size-fits-all' approach to regulating and inspecting pharmacies will not work going forward. We must continue to develop and improve our approach to keep pace with developments in pharmacy.
- 3.4. Improving the way we gather, use and share information is central to our strategic approach to regulating registered pharmacies, and reflects the Council's commitment to make better use of data and insights. Our new approach will increasingly use our data and insights to effectively target our resources where they can have the greatest impact, with our routine inspections increasingly informed by risk. Our new programme of inspections will be open, transparent and fair, with the same standards applied to all contexts.
- 3.5. The most significant change for both patients and the public and for pharmacy owners will be the introduction of publication of inspection reports. We believe that publishing inspection reports will strengthen the assurance we give to the public that pharmacies are providing safe and effective services and care. It will also help to drive continuous improvement within pharmacies, by shining a light on the outcomes of inspections and sharing information that will help the sector to learn and improve.

4. Key proposals

4.1. This consultation seeks views on our proposals to further develop our approach to regulating registered pharmacies.

We are proposing the following key changes:

- i. introducing new types of inspections
- ii. moving to unannounced inspections
- iii. changing inspection ratings
- iv. requiring all standards to be met to receive a 'met' rating
- v. publishing inspection reports
- vi. sharing examples of notable practice

4.2. Introducing new types of inspections

a) We are planning to move to a model that includes three types of inspections:

- i) **Routine inspections:** We will continue to carry out routine inspections of every pharmacy so that the public are assured that a pharmacy is continuing to meet our standards and to help the pharmacy identify how it can further improve the services it provides to patients. We will improve our approach by moving to a programme increasingly informed by risk indicators to identify which pharmacies we should inspect first. We will use a pharmacy's previous inspection rating as a proxy indicator of risk along with other relevant information we may hold, such as scale and complexity of services provided or change of ownership.
- ii) **Intelligence-led inspections:** We will ring-fence some of our existing resources to conduct inspections that are quickly initiated in response to intelligence that we have received from others, to make sure we are able to rapidly address risks or concerns raised with us.
- iii) **Themed inspections:** We plan to take forward a programme of themed inspections which will involve visiting a selection of pharmacies to focus on specific themes or issues, enabling us to better understand the underlying issues, their causes and effects. Composite reports will be published to inform

the sector on the issues and risks that have been found, and to inform discussions on how to continually improve pharmacy services in these areas.

- b) We are proposing to move from our current approach, where pharmacies are given advance notice that they will be inspected in the next four to six weeks, to one where inspections will be unannounced as a general rule. This would provide additional assurance that the outcome of an inspection more accurately reflects the extent to which a pharmacy is meeting the pharmacy standards on a day to day basis and the experience of patients and the public.

4.3. Changes to inspection ratings

- a) We are proposing to change our current model for inspection ratings. Concerns have been raised by stakeholders about the lack of clarity and differentiation between the current ratings, and we have previously committed to changing our current ratings model.
- b) We have listened to the feedback and have used this, and the learnings from focus groups with patients and the public, to inform our proposed approach, in which there would be only two possible outcomes from an inspection:
 - The pharmacy has met the standards for registered pharmacies – Met
 - The pharmacy has not met the standards for registered pharmacies – Not met
- c) There are 26 standards for registered pharmacies, which are grouped under five principles. For each of the five principles within the standards, pharmacies would receive one of four possible findings; 'standards not met', 'standards met', 'good practice' and 'excellent practice'. This will provide owners and their teams with a way to measure their performance, to support and drive improvement. It will also help to identify examples of good or excellent practice, as well as where standards are not met, which can be shared to help promote wider learning and improvement across the sector.
- d) The standards have now been in place for over five years. We are proposing that under our new approach, a pharmacy must meet all the standards to get an overall 'met' outcome. If a pharmacy does not meet a standard, this will result in an overall outcome of 'not met' the standards and there will be a mandatory improvement action plan.

4.4. Publication of inspection reports

- a) We are proposing to publish all inspection reports in the future, once we have the legal powers to do so and appropriate systems and processes are in place.
- b) As well as publishing reports from our individual inspections, and composite reports from our thematic inspections, we intend to publish examples of notable practice that have been identified through inspections. This includes examples that demonstrate both good or excellent practice as well as examples where standards are not being met. Sharing these examples of notable practice will provide a rich source of information that will inform the pharmacy sector and policy makers and will help to drive continuous learning and improvement.
- c) We have begun work to develop a new website where both patients and the public, and individuals and organisations from the pharmacy and health sectors, can access inspection reports. A key priority will be making sure the website is accessible to all and that the information within the reports is easy to search for and analyse.
- d) Examples of notable practice identified through inspections will be within a 'knowledge hub' within the website.

4.5. Future work:

- a) The consultation document also sets out further work we plan to carry out in future in relation to the regulation of registered pharmacies, including:
 - 1. Reviewing our standards for registered pharmacies to ensure they continue to prioritise patient care and the provision of safe and effective care
 - 2. Developing an enforcement policy to inform the way in which we use our enforcement powers.
 - 3. Seeking views on the information we collect about registered pharmacies, at the point of registration, at renewal and on-going basis
 - 4. Seeking views on a new appendix to our publication and disclosure policy which will cover the information we publish and disclose in relation to registered pharmacies.

5. Publishing a report of what we have learnt from our inspections, including sharing examples of notable practice
6. Considering whether we should continue to inspect all pharmacies on a rolling basis, or whether other options, such as sampling a cohort of pharmacies, would provide assurance to patients and the public that our standards for registered pharmacies are being met.

5. Equality and diversity implications

- 5.1. In all stages of our development work we have considered whether there are any significant equality implications, either positive or negative, for registrants or members of the public.
- 5.2. We have not identified any significant negative equality or diversity implications of our proposals so far and expect there to be a positive benefit for patients and the public.
- 5.3. We ask a specific question in the consultation relating to the potential impact of the proposals, including on people with protected characteristics, which will ensure we receive feedback on any relevant issues.
- 5.4. The consultation also asks wider questions on the impact of the proposals on the key groups who will be affected, and we will use the responses to inform a regulatory impact assessment
- 5.5. The requirements for the website include that it is easily accessible for all users, including people with disabilities. We are also planning to make inspection reports for pharmacies in Wales available in the Welsh language.
- 5.6. A draft EIA is being developed and will continue to be updated throughout the consultation process, and a final EIA will be presented to Council for approval following the consultation.

6. Communications

- 6.1. A comprehensive communications and engagement plan has been produced for the consultation. This sets out how we will use an integrated programme of communications and engagement activities to reach all key stakeholders through a variety of channels.
- 6.2. In advance of the consultation, we are holding a series of meetings with key stakeholders, to ensure they are briefed on our proposals and to seek their support in promoting the consultation through their networks. We are also planning a series of stakeholder events and meetings during the consultation with organisations and individuals representing patients and the public, pharmacy owners, pharmacy professionals and other key stakeholders, to provide the opportunity for in-depth discussions on our proposals.

- 6.3. The consultation will be also promoted through a letter to all pharmacy owners and through the GPhC website, our e-bulletin Regulate, a targeted email campaign and the media.

7. Resource implications

- 7.1. Resource implications of the consultation and of the implementation of the proposals within the consultation have been factored into budgets and resource plans across the organisation over this and the following financial years.

8. Risk implications

- 8.1. A risk register for the development and the implementation of the final proposals is being produced and will be regularly reviewed throughout the development and implementation of the proposals
- 8.2. The risks during the consultation and engagement phase have been mitigated by the production of a comprehensive communications and engagement plan that sets out how we will engage with all stakeholders affected by the proposals.

9. Monitoring and review

- 9.1. The Council will receive a consultation analysis report in the second part of 2018 and, following that, a consultation response report at a later meeting on which to make decisions on how to proceed.
- 9.2. Once the final proposals have been implemented, we will continue to monitor and regularly review their impact, as we have done with the current approach.

Recommendations

The Council is asked to:

- I. agree for consultation our proposals on developing our approach to regulating registered pharmacies and introducing the publication of reports from inspections of registered pharmacies.
- II. agree to delegate the final approval of the consultation document to the Chair

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28 March 2018

Consultation on developing our approach to regulating registered pharmacies

April 2018

Contents

Foreword

About the GPhC

Overview

Background

Our strategic approach to regulating registered pharmacies

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Our future work

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Equality monitoring

The deadline for responding to this consultation is **20/07/2018**

Foreword

Pharmacies provide us and our families with vital services that help us to maintain and improve our health and well-being. We all want assurance that the services we receive will be safe and effective.

As the pharmacy regulator, we have an important role in providing this assurance. We also want to drive continuous improvement in the quality of care that people receive when accessing pharmacy services.

Over the last five years we have made significant improvements to how we regulate registered pharmacies, introducing new 'outcome focussed' standards for registered pharmacies and implementing a new approach to inspecting pharmacies, which we have continued to refine and improve.

We now want to take the next step in developing our regulatory approach to provide greater assurance that pharmacies are meeting standards and to further drive continuous improvement in the quality of services patients and the public receive from registered pharmacies.

We know that the vast majority of pharmacies are meeting our standards, and we have found that those that aren't quickly make the necessary improvements.

Through engagement with patients and the public, pharmacy owners and the wider pharmacy team, including pharmacy professionals, we have heard that the changes we have made so far are welcome and are working well in practice. But we have also heard that there are opportunities to further develop our approach and improve our ability to achieve our two aims of assurance and improvement.

Our approach to regulating registered pharmacies cannot stand still. We have to continue to develop how we regulate in response to the ongoing changes we are seeing in how pharmacy services are delivered. We are increasingly seeing the introduction of new service models and a greater use of technology, and we do not expect the pace of change within pharmacy to slow down at any point in the future.

So, it is clear that a 'one-size-fits-all' approach to regulating and inspecting pharmacies will not work going forward. We plan to make our approach more flexible, agile and responsive. We propose introducing a differentiated approach with new types of inspections and to use information and intelligence to target our resources more effectively to help us achieve this.

The most significant change proposed in this consultation is for us to begin publishing inspection reports. Publication is, in our view, a game-changer. It will enable us to provide much more assurance to patients and the public and to those working across pharmacy and health that pharmacies are meeting standards providing safe and effective services. We also believe that publishing reports in an accessible way will help to drive continuous

improvement within pharmacy, by shining a light on the outcomes of inspections and sharing examples of practice that everyone in pharmacy can use to learn and improve. Publication also signifies a shift, where pharmacy owners can take responsibility for learning and improvement through a website that is designed to enable to self-service.

We want to know your views on whether our proposals will achieve the aims we set out in this document and what the impact will be for pharmacy owners, the pharmacy team, and, most importantly, the people using pharmacy services.

Nigel Clarke

Chair

Duncan Rudkin

Chief Executive

About the GPhC

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

Our main work includes:

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

Overview

We are consulting until **XXX 2018** on developing our approach to regulating registered pharmacies.

This consultation seeks views on our proposals to further develop our approach to regulating registered pharmacies. It is primarily focussed on:

We are proposing the following key changes:

1. **introducing new types of inspections;** we are planning to move to a differentiated model that includes three types of inspections; routine inspections, intelligence-led inspections and themed inspections. This will help us to ensure we are more agile and responsive to information we hold, intelligence we receive and issues we identify within pharmacy
2. **moving to unannounced inspections;** we are proposing that inspections will be unannounced as a general rule in the future, to ensure the outcomes reflect whether the pharmacy is meeting the standards every day
3. **changing inspection ratings;** we are proposing to change our current model for inspection ratings, so there would be two possible outcomes for an inspection overall ('met' or 'not met'), and four possible findings at the principle level ('not met', 'met', 'good practice' and 'excellent practice')
4. **requiring all standards to be met to receive a 'met' rating;** if any standard was found not to be met, this would result in a 'not met' rating overall
5. **publishing inspection reports;** we are planning to publish inspection reports, and improvement action plans where relevant, on a new website, which will be designed so that the information is easy to search and analyse
6. **sharing examples of notable practice;** we will also publish examples of notable practice that we identify through inspections in a 'knowledge hub' on the new website, to help drive continuous learning and improvement in pharmacy

We have grouped these proposals under three headings. We also want to hear views about the impact of our proposals on patients and the public, pharmacy owners and the wider pharmacy team.

We welcome responses from anyone with an interest in the regulation of pharmacies but are particularly interested to hear the views of patients and the public, pharmacy owners, members of the pharmacy team and individuals and organisations working in the wider pharmacy and health sectors.

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive. Our governing council will receive the analysis at a meeting in the second half of 2018. It will take the responses into account when making decisions on how to develop our approach to regulating registered pharmacies, and when the new approach will be implemented. We will also publish a summary of the responses and an explanation of the decisions taken. You will be able to see this on our website www.pharmacyregulation.org

How to respond

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

You can fill in the questionnaire at the end of this document or go to www.pharmacyregulation.org/ADDLINK and fill in an online version there.

If you fill in the questionnaire in this document, please send it to: consultations@pharmacyregulation.org with the subject 'Registered pharmacies consultation' or post it to us at:

Registered pharmacies consultation response

Inspection team

General Pharmaceutical Council

25 Canada Square

London

E14 5LQ C

Comments on the consultation process itself

If you have concerns or comments about the consultation process itself, please send them to: feedback@pharmacyregulation.org or post them to us at:

Governance Team

General Pharmaceutical Council

25 Canada Square

London

E14 5LQ

Please do not send consultation responses to this address.

Timeline: modernising our approach to regulating registered pharmacies



2012

Held consultation on 'Modernising Pharmacy Regulation'.

2012

Introduced new 'outcome-focussed' **Standards for registered pharmacies**.



2013

Introduced 'Show and Tell' approach to inspections, seeking assurance on how well the standards for registered pharmacies are met. Provided a 'rating' for each registered pharmacy. Identified where standards are not met and required the development and implementation of an action plan.

2015

Published an **Update paper** setting out our commitment to refine and improve our approach to inspections.



2015

Published ICF evaluation of the GPhC approach to regulating community pharmacies.



2018

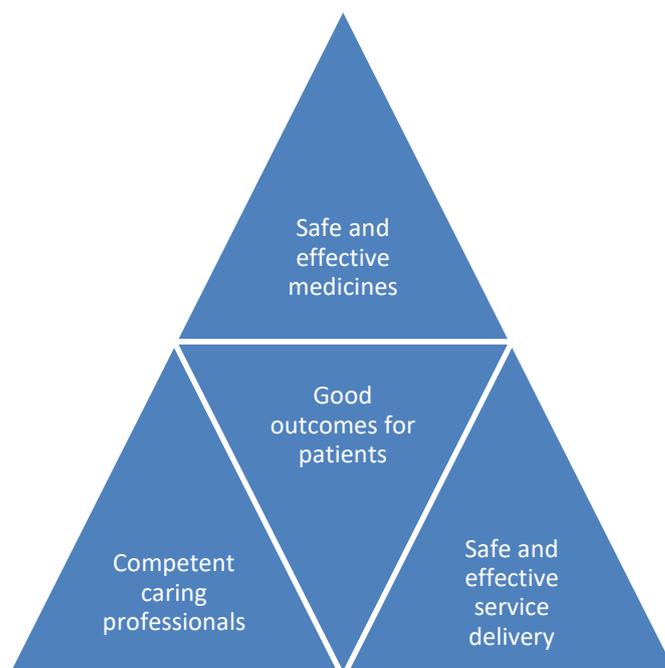
Now seeking views on further developments to the way we regulate and inspect registered pharmacies.



1. Background

- 1.1 In 2012, we set out a new vision for the regulation of registered pharmacies in our consultation on Modernising Pharmacy Regulation. In that consultation, we set out the three key components that we believe are needed for patients and the public to receive safe, effective pharmacy services and care, which are represented below, in a 'public protection triangle':

Public Protection Triangle



- 1.2 The Medicines and Healthcare products Regulatory Agency has the regulatory responsibility for ensuring medicines are safe and effective. We have the regulatory responsibility for the other two components in the triangle:
- Ensuring pharmacy professionals are competent, caring and practising to the right standards
 - Ensuring the systems for managing and delivering pharmacy services are safe and effective
- 1.3 This consultation focuses on how we will further develop our approach to the third component in the triangle; ensuring safe and effective service delivery.

Outcome focused approach

- 1.4 In 2012 we set out a new vision for the regulation of pharmacies. We made clear our ambition for pharmacy regulation to move beyond a focus on legal compliance, check lists and standard operating procedures. Our aim was to develop new standards which all pharmacies registered with the GPhC would have to meet every day. The purpose of these standards is to create and maintain the right environment, both organisational and physical, for the safe and effective

practice of pharmacy. These standards put patients first, describing the things that pharmacies need to deliver – or ‘outcomes’ – rather than publish a long list of prescribed rules from the regulator.

- 1.5 Following the introduction of these new ‘outcome focussed’ standards, we developed and implemented a new approach to inspection in 2013. This marked a significant change from the previous tick-box approach and narrow focus on rules and regulations and processes. Since then, our inspections have been based on a ‘show and tell’ approach. Our inspectors look at all the pharmacy services being provided and involve the whole pharmacy team in the inspection process to be assured that the standards for registered pharmacies are being met. Inspectors also speak to all of the team to make sure they are aware of the standards and how the way they work has an impact on the services provided and on the public that use and receive pharmacy services.
- 1.6 Inspectors prepare reports for pharmacy owners and superintendents detailing the GPhC’s judgement of how well their pharmacy is meeting the standards. Improvement action plans are a regulatory intervention that is required if one or more standards are not being met and we follow up with the pharmacy to make sure necessary improvements are made.

Evaluating our approach

- 1.7 In February 2015, we published an update paper, *Modernising Pharmacy Regulation: from prototype to implementation*, which highlighted the progress that had been made to modernise pharmacy regulation, including through the introduction of the new model of inspection. The paper also highlighted those areas where we were planning to adapt and change our model in the future, including in relation to ratings of inspections. The paper committed to consulting on proposed changes later, once there had been progress on the required legislative changes (which are expected to be commenced shortly).
- 1.8 We also commissioned an external evaluation, by ICF International, of our approach to regulating community pharmacies in 2015 which concluded that our approach was perceived to be working well. The standards for registered pharmacies were generally well-understood and there was also widespread agreement that inspection reports help pharmacy owners to improve the services provided to patients and the public. Developing improvement action plans when one or more standards were not met also helped pharmacy professionals focus on the issues of most importance to patients.
- 1.9 The study also highlighted some feedback for us to consider. Some concerns were expressed about the ratings model, with some suggesting there was a lack of clarity and differentiation between ratings, with particular concerns raised about the use of the term ‘satisfactory’.

New legal powers

- 1.10 In 2015, the Department of Health consulted on draft legislation to give us new powers to regulate registered pharmacies. The responses to that consultation were published in a report in February 2016. There was overwhelming support for the proposals in the consultation,

including in relation to publication and enforcement; 91% of respondents supported the proposals in relation to the publication of the outcomes of inspections, and 94% supported the approach to be taken by the regulators to breaches of pharmacy premises standards by pharmacy owners.

- 1.11 The new legislation (the Pharmacy (Premises Standards, Information Obligations etc) Order) was agreed in 2016 and is expected to come into effect in shortly.

Ongoing engagement

- 1.12 Since 2015, we have continued to seek feedback on our approach from stakeholders across pharmacy, as well as patients and the public. We have also shared what we have learnt about our approach in a range of stakeholder events and meetings, as well as through articles highlighting good practice in our e-bulletin, Regulate.

- 1.13 We held focus groups with patients and the public in December 2017 to seek their views on how we plan to develop our approach, including the publication of inspection reports. There was clear agreement among participants that reports from pharmacy inspections should be published and should be easily accessible to the public, and overall support for our proposed approach.

- 1.14 We have used what we have heard through our ongoing engagement, including these focus groups, to develop the proposals in this consultation.

Findings from inspections

- 1.15 Since we introduced the new 'show and tell' approach to inspections, we have inspected 12,825¹ registered pharmacies across Great Britain. Of those inspected 85% were found to be meeting all the standards for registered pharmacies. Those that weren't were required to develop an improvement action plan. Our own analysis suggests that improvement action plans are working well in practice- 99% of pharmacies which had to complete improvement action plans in 2016/17 made the necessary improvements.²

- 1.16 We expect to have inspected every registered pharmacy in Great Britain by summer 2018. By the end of 2018, we will publish a report of what we have learnt from our inspections, including sharing some examples of notable practice (including examples of good and excellent practice as well as where standards have not been met).

Developing our approach

- 1.17 It is important that we remain agile and flexible, and that our regulatory approach adapts to the changes in pharmacy, including how services are delivered. We have reflected on what we

¹ From 1 November 2013 to 1 March 2018

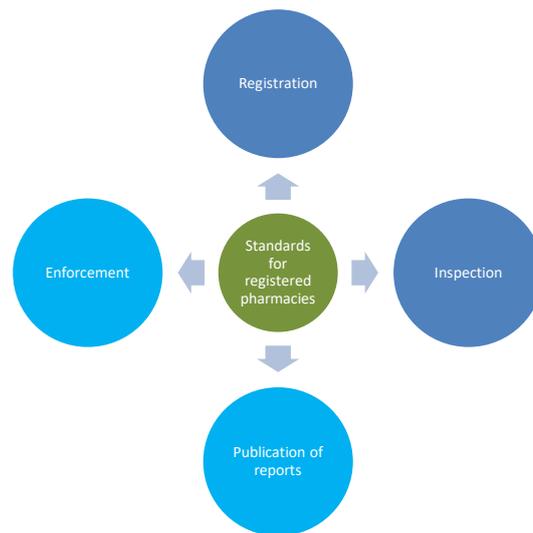
² *The remaining one per cent is made up of plans where actions were not yet due, or where they had long lead times

have learnt and want to further improve our regulatory approach and take the next step to further drive improvement at an individual pharmacy level, but also throughout the pharmacy sector by sharing our learning and insights from inspections. Our proposals will mean that patients and the public can continue to be assured about the quality, of which safety is a critical element, of the pharmacy services provided at or from registered pharmacies.

2. Our strategic approach to regulating registered pharmacies

- 2.1 We believe that pharmacy regulation has a significant role to play in quality improvement – of which safety is a critical element – in pharmacy practice and ultimately health and wellbeing in England, Scotland and Wales. Our strategy sets out what we want to achieve in two words; assurance and improvement. This means providing assurance that the standards for registered pharmacies are being met in every pharmacy across Great Britain and driving continuous improvement in the quality of services and care for the public.
- 2.2 Our approach to regulating registered pharmacies focusses on both assurance and improvement because we believe that patients and members of the public expect and want more than just assurance that standards are being met. They want assurance that pharmacy owners are continually working to improve the quality and experience of care that they, the users of pharmacy services, receive.
- 2.3 The registered pharmacies we regulate are diverse in nature. Registered pharmacies provide a wide range of services to patients and the public and are located in many different environments – from busy shopping centres in large cities to small villages. Pharmacy services are provided to patients with differing healthcare needs, some may have long term conditions whilst others may visit a pharmacy far less frequently. NHS contractual obligations vary across England, Scotland and Wales as do funding structures. Pharmacies are increasingly playing a bigger role in supporting and maintaining the health and well-being of the people using their services, with many pharmacies now offering a range of new health services. And we know that technology, and the increased use of digital communications, will continue to influence the way in which services are provided in the future.
- 2.4 It is therefore critical that the way we regulate registered pharmacies does not stand still. Our approach to regulating pharmacies must be equally flexible and agile. And we must continue to refine and improve our approach to keep pace with developments in pharmacy and believe that an outcome focussed approach is still the only way to do this.
- 2.5 We also want to make sure we do not stand in the way of responsible innovation and take a proportionate approach that is fair to those we regulate. We will make sure we consider the context in which each pharmacy is working and apply the standards to all contexts.
- 2.6 Improving the way we gather, use and share information is central to our strategic approach to regulating registered pharmacies, and reflects our Council’s commitment to make better use of data and insights. Our new approach will be increasingly informed by information and intelligence, using our data and insight to effectively target our resources where they can have the greatest impact. We know we are in a unique position because through our inspections we see many areas of notable practice in pharmacy. Therefore, sharing what we learn from inspections is also central to our new approach and to helping us ensure that patients and the public receive safe and effective care. Publishing inspection reports will strengthen the assurance we give to the public that pharmacies are providing safe and effective services and care. It will also help to drive continuous improvement within pharmacies, by shining a light on the outcomes of inspections and sharing information, in an accessible and interactive way. We believe this will empower pharmacy to learn and improve.

3. How we regulate registered pharmacies



3.1 There are several ways in which we regulate registered pharmacies:

- a. Through **registration** we are clear about the criteria that must be met for a pharmacy to be registered with us, and this includes demonstrating how the standards for registered pharmacies will be met.
- b. We set **standards** for registered pharmacies, which make clear the expectations on owners of pharmacies and the outcomes that must be met to ensure that patients and the public receive safe and effective care. There are 26 standards for registered pharmacies, and these are grouped under five principles: governance, staff, pharmacy premises, management of medicines and equipment and facilities.
- c. We seek and provide assurance that the standards for registered pharmacies through our **inspections**. Inspection also plays an important part in ensuring that the quality of pharmacy services improves, by:
 - a. Providing feedback on how a pharmacy meeting the standards could further improve the quality of their services, including by highlighting examples of good or excellent practice and
 - b. Ensuring that improvements are made by the pharmacy owner when the standards for registered pharmacies are not being met
- d. We will shortly have powers to **publish** inspection reports. We have from the outset stated our intention to publish inspection reports. One of the core principles of good regulation is that we should be open and transparent; and we believe that publication of inspection reports will provide further assurance to patients and the public that pharmacies are meeting standards and providing safe and effective care, whilst also providing further opportunities for pharmacy owners to improve the quality of pharmacy services.
- e. We will have several **enforcement tools** that we can use to ensure that pharmacy services delivered at or from a registered pharmacy are safe and effective. This includes improvement notices, conditions, interim suspensions, removal of a pharmacy or pharmacies from the register and disqualification powers for owners. We will ensure that decisions about when to use our enforcement powers are made consistently and proportionately. This means that we will reserve our statutory enforcement powers for

those situations where a pharmacy owner does not complete an improvement action plan and undertake necessary changes to ensure our standards are met, or for those situations where there is a serious risk to patient safety.

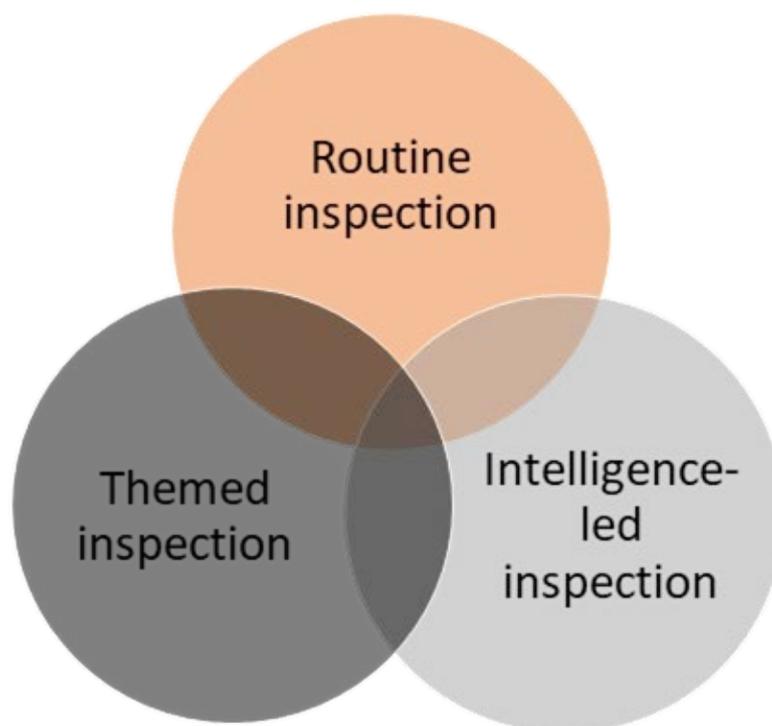
- f. We will continue to follow the principle that each of our registrant groups, including owners of registered pharmacies, should bear the costs of regulating that group through the fees they pay. We will continue to review the costs of regulation and allocate fees fairly and proportionately.

Our proposals

4. Introducing new types of inspections

- 4.1 We are improving our approach to inspections to ensure that we are agile and responsive. We will use three types of inspections which we can use flexibly in different situations. This allows us to be more responsive when we need to be, and enables us to look at specific issues in pharmacy and services in greater detail. We believe that our proposals strengthen both our ability to provide assurance to the public and to encourage pharmacy owners to continually improve the quality of services they provide. We will continue to routinely inspect every registered pharmacy in Great Britain.

Types of inspection



Routine inspections

- 4.2 Routine inspections provide assurance to patients and the public that the standards for registered pharmacies continue to be met. We are improving our approach to ensure our programme of inspections are increasingly more flexible and effective and informed by indicators of risk when identifying which pharmacies should be inspected first.
- 4.3 This means that we will first inspect those pharmacies previously rated as 'poor', followed by those rated as 'satisfactory with an action plan'. Once we have inspected those pharmacies which previously had action plans, we will inspect the pharmacies rated as 'satisfactory'

(without an action plan), followed by those rated as 'good' and then 'excellent'. This will also enable us to evaluate whether previous improvements have been sustained.

- 4.4 There will be other indicators that we will also factor into our consideration of which pharmacies should be inspected first. These may include when there has been a change of ownership or significant changes to the governance structures of a pharmacy, or where the scale or complexity of services offered is significant or changed. These factors may indicate that an inspection should be conducted earlier on in the new programme.
- 4.5 As is the case now, if one or more of the standards is not met, the pharmacy owner will have to develop an improvement action plan setting out what they will do to rectify the issues and meet the standards for registered pharmacies. We will continue to follow up with these pharmacies to make sure that the necessary improvements are made and that the standards are fully met.

Intelligence-led inspections

- 4.6 We often receive information about pharmacies from others, including regulators, healthcare professionals and the public, as well as from journalists and the media. We already use this information to prioritise an inspection, for example if there are concerns about the quality or safety of pharmacy services. We also receive information through concerns raised about pharmacy professionals which could provide intelligence about a pharmacy or pharmacies.
- 4.7 We plan to ring-fence some of our existing resources to make sure that we can be more responsive and are able to rapidly address risks or concerns raised with us.
- 4.8 We also know that our ability to carry out intelligence led inspections will grow over time as we get better at using the information we receive from others. We will be able to see some of the patterns and trends that create problems for pharmacies, and this in turn will inform how we prioritise our future routine inspections.

Themed inspections

- 4.9 We plan to take forward a programme of themed inspections which will involve visiting a selection of pharmacies to focus on specific themes or issues in more depth. For example risk management of supplying medicines online, or services provided to a care home.
- 4.10 Themed inspections may also be informed by the issues and risks identified by our routine and intelligence led inspections. These inspections will be flexible and enable us to be responsive to emerging risks and future developments in the provision of pharmacy services by allowing us to better understand the underlying issues, their causes and effects.
- 4.11 Themed inspections may be adapted to take place across organisational boundaries and health systems. They are likely to involve inspection of a number of pharmacies. We expect to

use two or more inspectors to carry out a themed inspection sometimes with the help of experts from other organisations.

- 4.12 We believe that these inspections will drive improvement in the quality of pharmacy services, by identifying learning and good practice that can be shared across pharmacy and enabling other pharmacy owners to learn and improve the quality of the services they provide. These inspections will also inform our own regulatory work, and the development of guidance.

Do you think the three types of inspection will:

	Yes	No	Don't know
provide more assurance that pharmacies are meeting our standards?			
enable us to be more responsive and agile to risks or changes in pharmacy or healthcare?			
help to drive improvements through identifying and sharing good practice?			

Please provide comments explaining your responses

Do you have any other comments about the types of inspections?

Unannounced inspections

- 4.13 Currently, we write to pharmacy owners in advance of an inspection, we tell them that we will inspect their registered pharmacy within the next four to six weeks. We have heard from patients and the public during focus groups that they would welcome unannounced inspections, as this provides additional assurance that the outcomes of an inspection more accurately reflect the extent to which a pharmacy is meeting our regulatory standards on a day to day basis and the experience of patients and the public.
- 4.14 We recognise that pharmacy owners and superintendent pharmacists may want to be present during an inspection, but we want to ensure that inspection will reflect the experience

patients and the public have on that particular day, and the pharmacy should be meeting the standards every day.

- 4.15 We are therefore proposing that inspections will be unannounced as a general rule. However, we know there may be situations where it is not possible for us to inspect a pharmacy unannounced, for example where a registered pharmacy is in a prison or other secure environment. Likewise, we believe that themed inspections, which look at specific issue involving a number of pharmacies and a team of inspectors, **will need to be scheduled in advance.**

Will moving from announced to unannounced inspections as a general rule provide greater assurance that pharmacies are meeting our standards?

Yes / No / Don't know

Please provide comments explaining your response

We have identified instances when it may not be possible to have an unannounced inspection. Are there any other instances we need to consider?

Yes / No / Don't know

Please provide comments explaining your response

Do you have any other comments on us carrying out unannounced inspections as a general rule?

5. Changes to inspection ratings

- 5.1 Under our existing model, pharmacies receive an overall rating of their performance, the outcome of which may be poor, satisfactory, good or excellent.
- 5.2 We know from the research we commissioned and the feedback we received that there were concerns about the ratings. In particular, lack of clarity and differentiation between these outcomes, and the terminology satisfactory. The research suggested two possible solutions. One solution was to introduce a scoring system with more grades available. The other solution was to introduce a simpler pass or fail rating which had limited scope for misinterpretation.

- 5.3 We want to ensure the overall rating of an inspection is clear to patients and the public and pharmacy owners whether a pharmacy has met, or not met the standards. Our approach to the overall outcome is:
- **Standards met** (the pharmacy has met the standards for registered pharmacies) or
 - **Standards not met** (the pharmacy has not met the standards for registered pharmacies)
- 5.4 We believe that this approach will provide clear, simple assurance, rather than introducing more opportunities for ambiguity with more grades. We tested this approach with patient and public focus groups in 2017 where there was broad agreement that these outcomes were clear and simple to understand.
- 5.5 We will also continue to provide a finding for each of the five principles in the standards for registered pharmacies too, because this provides us, owners and their teams with a way to measure their performance. We believe this approach supports and drives continuous improvement in the quality of pharmacy services for patients and the public.
- 5.6 There was broad agreement in the public and patient focus groups that it was important to understand how well the pharmacy had done under each principle. So, our inspection reports will make one of four findings at principle level:
- **standards not met**
 - **standards met**
 - **good practice, and**
 - **excellent practice**
- 5.7 Under our new approach, a pharmacy must meet all the standards to get an overall rating that the pharmacy has met the standards for registered pharmacies. If a pharmacy has not met a standard, this would result in a 'standards not met' rating overall. The standards have been in place for five years. Patients expect that if a pharmacy receives a 'met standards' rating that they have met all the standards.
- 5.8 As is the case now, inspectors will use their judgement based on the evidence they collect at the pharmacy to decide whether a standard has been met or not. They use the inspection decision making framework to help them do that. When considering whether a standard has been met, the inspector will consider the impact and scale of the area for improvement and the greater the impact on patient safety, the more likely it is that the standard will not be met. Relatively minor non-compliance is unlikely to result in a standard not being met, as is the case now.
- 5.9 Where a pharmacy does not meet the standards this will mean that the pharmacy owner will be required to complete an improvement action plan. The improvement action plan is a regulatory tool, it documents the steps that a pharmacy owner will take to ensure that the standards which have not been met initially will be met and importantly includes a date by which the improvements will be made.

5.10 Once the pharmacy owner has advised that they have completed the improvement action plan, it may be necessary for the inspector to re-visit the pharmacy to review if the necessary improvements have been made. Once the inspector is satisfied that the pharmacy is meeting the standards and improvements are being sustained, the pharmacy owner will be informed that the improvement action plan has been completed and there will be no statutory enforcement action. An updated overall rating and report will be provided to the pharmacy.

Will the changes to inspection ratings make it clear to patients, the public and pharmacy owners whether a pharmacy has met, or not met, the standards?

Yes / No / Don't know

Please provide comments explaining your response

Do you think that having four findings (not met, met, good practice and excellent practice) for each of the principles will:

	Yes	No	Don't know
provide owners and their teams with a way of measuring their performance?			
continue to drive improvement?			

Please provide comments explaining your responses

Do you think that not meeting one standard should result in the pharmacy receiving an overall rating of 'not met'?

Yes / No / Don't know

Please provide comments explaining your response

Do you have any other comments on the changes we are proposing to inspection ratings?

6. Publication

- 6.1 We have stated publicly that we intend to publish all inspection reports once we were given the explicit legislative powers to do so. Publication of inspection reports is necessary for four main reasons:
1. we should be open and transparent about not only the outcome an inspection, but also the evidence we have gathered to come to that decision;
 2. the publication of inspection reports will provide clear assurance to the public that pharmacies have met the standards for registered pharmacies;
 3. publication will enable the pharmacy sector as a whole to use the information in the reports to improve;
 4. the publication of inspection reports will align with the approach taken in other healthcare services.
- 6.2 We believe publication of inspection reports will empower patients and the public and pharmacy. The transparency of information will provide assurance to patients and the public that pharmacies are meeting our regulatory standards will provide the sector with a rich source of information to inform policy makers and to drive continuous improvement.

Inspection reports

- 6.3 We will publish all inspection reports, following a routine or intelligence led inspection in the future. An inspection report will include a summary report, that will contain a link to the detailed report that contains the evidence of what was found and examples of notable practice.
- 6.4 We will also publish the improvement action plan which explains the actions the pharmacy owner will take to ensure that they meet the standards for registered pharmacies. Examples of a summary report, a detailed report and an improvement action plan are available on our website. Every routine or intelligence led inspection will result in both a summary and detailed report. Inspections reports will not contain commercially sensitive or patient identifiable information.
- 6.5 The summary report will be the primary source of information that the public will see on the website. It is a plain English version of the detailed report and contains a summary of the overall outcome, the findings at principle level and links to any improvement action plan.
- 6.6 The detailed report will contain the evidence that supports the overall outcome and the findings at principle level. The primary audience for the detailed report will be the owner and superintendent. The detailed report will be available to the public through a link on the summary report.
- 6.7 Our proposals have been informed by feedback from patients and the public during focus groups held in 2017. At the focus groups, we explained our plans to publish reports in future and shared examples of what the reports may look like.

- 6.8 Participants found the draft reports to be clear and easy to read, and said they contained the information they would expect and would find relevant to them. There was general agreement that members of the public would usually only want to read the summary report from the inspection, but the view was also expressed that the more detailed report should also be available via a link from the summary report. It was also suggested by participants in the focus groups that where the pharmacy had to complete an improvement action plan with timelines for the improvements to be made, this should be available through a link in both the summary and detailed reports.
- 6.9 The reports we publish following a themed inspection will not include individual outcomes for the registered pharmacies involved. This type of inspection explores specific issues in the way a pharmacy works or aspects of services it provides. These reports, which will be published on the web site, will be interactive and engaging with the information readily accessible as a source of learning for pharmacy as a whole.
- 6.10 There was a clear consensus among participants in the focus groups with patients and the public that they would also want to see the outcome of the inspection clearly displayed in the pharmacy itself. We plan to explore options for supplying a sign or sticker showing the inspection outcome to pharmacies following an inspection. This would give a clear indication to people using that pharmacy as to whether the pharmacy met our standards during its last inspection.

Do you think we should publish inspection reports?

Yes / No / Don't know

Do you think publishing inspection reports will:

	Yes	No	Don't know
provide greater transparency about the outcome of an inspection?			
provide clear assurance to users of pharmacy services that pharmacies have met the standards?			
enable the pharmacy sector as a whole to use the information in the reports to improve?			

Please provide comments explaining your responses

Do you have any suggestions about the intended format and content of the summary, detailed and themed inspection reports?

We are proposing to publish improvement action plans in order to be open and transparent about all aspects of our inspection process.

Do you think we should publish improvement action plans?

Yes / No / Don't know

Please provide comments explaining your response

The website and knowledge hub

- 6.11 Publication of inspection reports will only drive improvements in the quality of pharmacy services and care if the way in which we publish inspection reports is accessible and enables people to easily find and analyse information they can use to learn and improve.
- 6.12 We are designing a new website that will host our inspection reports after publication. We are focusing the development of the website on ease of accessibility, equality principles and the user experience. We envisage that the inspection reports will be searchable by post code, pharmacy name, type of pharmacy, through a map, inspection outcomes, by principle or by standards.
- 6.13 The summary report will be the primary source of information on the website containing a summary of the overall outcome, the findings at principle level and links to the detailed report and improvement action plan where applicable. The detailed report will contain the evidence that underpins the overall outcome and the findings at principle level. It also identifies areas of notable practice, which is practice that demonstrates both good and excellent practice, as well as examples where standards are not being met.
- 6.14 These areas of notable practice will generate case studies from which others may learn and these will sit within an online knowledge hub. Our intention is that the hub will comprise a rich source of learning primarily for the sector drawn from those notable exception standards to learn from. The site will be interactive and searchable on a self-service basis. Finally, we will also publish inspection reports alongside the entry of the pharmacy on the online register.

Do you think the interactive website and knowledge hub will:

	Yes	No	Don't know
make information easily accessible			

encourage the sharing of knowledge within the pharmacy sector?			
enable learning from examples of poor, good and excellent practice?			
drive improvements within pharmacy?			

Please provide comments explaining your responses

Quality assurance of inspection reports

6.15 It is important that we publish all inspection reports as soon as we can after each inspection. We believe that unnecessary delays will undermine assurance that we provide to patients and the public. However, we must also make sure that patients and the public, as well as pharmacy owners are confident about the content and quality of inspection reports. Therefore, for all routine and intelligence-led inspections we will continue to:

- send the inspection reports to the pharmacy owner in advance to check the factual accuracy of the report before publication;
- ensure that every inspection report is subject to quality assurance; and
- develop a process for reviewing the overall outcome of an inspection, in the event that a pharmacy owner challenges our decision making on factual accuracy grounds;
- notify the pharmacy owner in advance of the publication of the inspection report

6.16 We will publish inspection reports in a managed and systematic way. We will publish reports in batches either weekly or monthly.

6.17 The nature of themed inspections (which may involve a cross organisational inspection of a significant number of pharmacies) means that the subsequent report will necessarily take longer to prepare, and quality assure. These reports will also be published on our website.

Do you have any comments about the process for quality assuring the reports?

7. Impact of the proposals

What kind of impact do you think the proposals will have on people using pharmacy services?

Positive impact / Negative impact / No impact / Don't know

Please provide comments explaining your response

What kind of impact do you think the proposals will have on owners of registered pharmacies?

Positive impact / Negative impact / No impact / Don't know

Please provide comments explaining your response

What kind of impact do you think the proposals will have on the pharmacy team?

Positive impact / Negative impact / No impact / Don't know

Please provide comments explaining your response

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

Age;

Disability;

Gender reassignment;

Marriage and civil partnership;

Pregnancy and maternity;

Race;

Religion or belief;

Sex; and

Sexual orientation.

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

Yes / No / Don't know

Please describe the impact and the individuals or groups concerned

Our future work

Whilst the main focus of this consultation is on inspections and the publication of inspection reports, we are committed to taking forwards work on other improvements to the way in which we regulate registered pharmacies. We will, in the future:

1. Review our standards for registered pharmacies to ensure they continue to prioritise patient care and the provision of safe and effective care. We know that the Department of Health intends to seek views on giving the pharmacy regulators in the UK the power to set standards for superintendent pharmacists. We will await the outcomes of this consultation. If there is support for the government's proposals, we will review the standards for registered pharmacies alongside standards for superintendent pharmacists.
2. We will develop an enforcement policy to inform the way in which we use our enforcement powers and will seek views on any future guidance for statutory committee decision making.
3. We will seek views on the information we collect about registered pharmacies, at the point of registration, at renewal and on-going basis
4. We will seek views on a new appendix to our publication and disclosure policy which will cover the information we publish and disclose in relation to registered pharmacies. This will include the length of time that reports remain on our website.
5. We will publish a report of what we have learnt from our inspections, including sharing examples of notable practice (including good and excellent examples of practice as well as examples of practice that fall below the expected standard).
6. We want to ensure that we continue to use our resources effectively, and therefore we will consider whether we should continue to inspect all pharmacies on a rolling basis, or whether other options, such as sampling a cohort of pharmacies, would provide assurance to patients and the public that our standards for registered pharmacies are being met.

Next steps

After the consultation closes, we will analyse what we have heard through the consultation, focus groups and face to face meetings. Our Council will consider the feedback before making decisions on our proposals.

We will clearly communicate the decisions that our Council make and anticipate beginning the publication of inspection reports in the first part of 2019, subject to Council's approval.

The consultation process

How to respond

You can respond to this consultation in a number of different ways. You can fill in the questionnaire at the end of this document or go to www.pharmacyregulation.org/XXX and fill in an online version there.

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

consultations@pharmacyregulation.org with the subject 'XXX consultation'

or post it to us at:

XXXX Consultation response

XXXX Team

General Pharmaceutical Council

25 Canada Square

London E14 5LQ

Comments on the consultation process itself

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

feedback@pharmacyregulation.org

or post them to us at:

Governance Team

General Pharmaceutical Council

25 Canada Square

London E14 5LQ

Please do not send consultation responses to this address.

Our report on this consultation

Once the consultation period ends, we will analyse the responses we receive. Our governing Council will receive the analysis at a meeting in the second half of 2018. It will take the responses into account when considering changes to the way in which we regulate registered pharmacies.

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

How we will use your responses

Responding as an individual:

If you respond as a private individual, we will not list your name in the published report or publish your response.

Responding on behalf of an organisation:

If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you want any part of your response to stay confidential, you should explain why you believe the information you have given is confidential.

Occasionally, the GPhC may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). On these rare occasions, the GPhC will usually anonymise responses or ask for consent from respondents, but please be aware that we cannot guarantee confidentiality.

If you email a response to the consultation and this is covered by an automatic confidentiality disclaimer generated by your IT system this will not, in itself, be binding on the GPhC.

Consultation response form

Background questions

First, we would like to ask you for some background information. This will help us to understand the views of specific groups, individuals and organisations and will allow us to better respond to those views.

Are you responding:

- as an individual – please go to section A
- on behalf of an organisation – please go to section B

Section A – Responding as an individual

1. Please tell us your:

- name:
- address:
- email:

2. Where do you live?

- England
- Scotland
- Wales
- other (please give details)

3. Are you responding as:

- a pharmacist
- a pharmacy technician
- a pharmacy owner who is not registered as a pharmacist or pharmacy technician (please go to question 5)
- a member of the pharmacy team who is not registered with the GPhC (for example, a dispenser or counter assistant) (please go to question 6)
- a member of the public (please go to Section C – Consultation questions)
- other (please give details) (please go to Section C – Consultation questions)

4. Are you:

- a pharmacy owner
- a superintendent pharmacist (please go to question 6)
- none of the above (please go to question 6)

5. Which of the following best describes the pharmacy you own?

- Sole trader
- Partnership
- Body corporate

6. Please choose the option below which best describes the area you mainly work in:

- community pharmacy (please go to question 8)
- hospital pharmacy
- primary care organisation (please go to Section C – Consultation questions)
- pharmacy education and training (please go to Section C – Consultation questions)

- pharmaceutical industry (please go to Section C – Consultation questions)
- other (please give details) (please go to Section C – Consultation questions)

7. Do you work in a registered pharmacy?

- Yes (please go to question 8)
- No (please go to Section C – Consultation questions)

8. Which of the following best describes your organisation?

- Independent pharmacy (1-5 pharmacies)
- Small multiple pharmacy (6-20 pharmacies)
- Large multiple pharmacy (Over 21 pharmacies)

Section B: Responding on behalf of an organisation

If you want any part of your organisation's response to stay confidential, please explain why you think the information you have given is confidential. We cannot give an assurance that confidentiality can be maintained in all circumstances.

Please keep parts of my organisation's response confidential

Please explain which parts you would wish to keep confidential and why:

1. Please tell us your:

- name:
- job title:
- organisation:
- address:
- email:
- a contact name for enquiries:

2. Is your organisation a:

- pharmacy organisation
- non-pharmacy organisation

3. Please choose the option below which best describes your organisation:

- organisation representing patients or the public
- organisation representing pharmacy professionals or the pharmacy sector
- independent pharmacy (1-5 pharmacies)
- small multiple pharmacy (6-20 pharmacies)
- large multiple pharmacy (Over 21 pharmacies)
- NHS organisation or group
- research, education or training organisation
- government department or organisation
- regulatory body
- other (please give details)

4. Please provide a brief description of what your organisation does and its interest in this particular consultation:

Section C - Consultation questions

Introducing new types of inspections

On pages XX/In section XX we describe the changes we plan to make to the types of inspections we carry out.

1a. Do you think the three types of inspection will:

	Yes	No	Don't know
provide more assurance that pharmacies are meeting our standards?			
enable us to be more responsive and agile to risks or changes in pharmacy or healthcare?			
help to drive improvements through identifying and sharing good practice?			

1b. Please provide comments explaining your responses

2. Do you have any other comments about the types of inspections?

Unannounced inspections

On pages XX/In section XX we describe our plans to move from announced to unannounced inspection visits as a general rule for routine and intelligence led inspections.

3a. Will moving from announced to unannounced inspections as a general rule provide greater assurance that pharmacies are meeting our standards?

Yes / No / Don't know

3b. Please provide comments explaining your response

4a. We have identified instances when it may not be possible to have an unannounced inspection. Are there any other instances we need to consider?

Yes / No / Don't know

4b. Please provide comments explaining your response

5. Do you have any other comments on us carrying out unannounced inspections as a general rule?

Changes to inspection ratings

On pages XX/In section XX we describe the changes we plan to make to the inspection ratings.

6a. Will the changes to inspection ratings make it clear to patients, the public and pharmacy owners whether a pharmacy has met, or not met, the standards?

Yes / No / Don't know

6b. Please provide comments explaining your response

7a. Do you think that having four findings (not met, met, good practice and excellent practice) for each of the principles will:

	Yes	No	Don't know
provide owners and their teams with a way of measuring their performance?			
continue to drive improvement?			

7b. Please provide comments explaining your responses

8a. Do you think that not meeting one standard should result in the pharmacy receiving an overall rating of 'not met'?

Yes / No / Don't know

8b. Please provide comments explaining your response

9. Do you have any other comments on the changes we are proposing to inspection ratings?

Publication

On pages XX/In section XX we describe our plans to publish individual inspection reports for routine and intelligence led inspections and a composite report for themed inspections.

10a. Do you think we should publish inspection reports?

Yes / No / Don't know

10b. Do you think publishing inspection reports will:

	Yes	No	Don't know
provide greater transparency about the outcome of an inspection?			
provide clear assurance to users of pharmacy services that pharmacies have met the standards?			
enable the pharmacy sector as a whole to use the information in the reports to improve?			

10c. Please provide comments explaining your responses

11. Do you have any suggestions about the intended format and content of the summary, detailed and themed inspection reports?

We are proposing to publish improvement action plans in order to be open and transparent about all aspects of our inspection process.

12a. Do you think we should publish improvement action plans?

Yes / No / Don't know

12b. Please provide comments explaining your response

The website and knowledge hub

On pages XX/In section XX we describe our plans to publish the reports on an interactive website and to introduce a knowledge hub for highlighting and sharing examples of poor, good and excellent practice.

13a. Do you think the interactive website and knowledge hub will:

	Yes	No	Don't know
make information easily accessible			
encourage the sharing of knowledge within the pharmacy sector?			
enable learning from examples of poor, good and excellent practice?			
drive improvements within pharmacy?			

13b. Please provide comments explaining your responses

14. Do you have any comments about the process for quality assuring the reports?

Impact of the proposals

15a. What kind of impact do you think the proposals will have on people using pharmacy services?

Positive impact / Negative impact / No impact / Don't know

15b. Please provide comments explaining your response

16a. What kind of impact do you think the proposals will have on owners of registered pharmacies?

Positive impact / Negative impact / No impact / Don't know

16b. Please provide comments explaining your response

17a. What kind of impact do you think the proposals will have on the pharmacy team?

Positive impact / Negative impact / No impact / Don't know

17b. Please provide comments explaining your response

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

Age;

Disability;

Gender reassignment;

Marriage and civil partnership;

Pregnancy and maternity;

Race;

Religion or belief;

Sex; and

Sexual orientation.

18a. Do you think anything in the proposed changes would impact – positively or negatively – on certain individuals or groups who share any of the protected characteristics listed above?

Yes / No / Don't know

18b. Please describe the impact and the individuals or groups concerned

Receiving updates

We would like to email you to update you on progress on this consultation as well as other work of the GPhC. Please tell us below if you would like to be contacted in the future.

- I would like to be contacted with updates related to the consultation on guidance to ensure a safe and effective pharmacy team
- I would like to be contacted with news and information about other consultations from the GPhC

Equality monitoring

At the GPhC, we are committed to promoting equality, valuing diversity and being inclusive in all our work as a health professions regulator, and to making sure we meet our equality duties.

We want to make sure everyone has an opportunity to respond to this consultation on developing our approach to regulating registered pharmacies. This equality monitoring form will provide us with useful information to check that this happens.

Your answers will not be linked to your consultation responses. You do not have to answer these questions if you would prefer not to.

What is your sex?

Please tick one box

- Male
- Female
- Other

What is your sexual orientation?

Please tick one box

- Heterosexual/straight
- Gay woman/lesbian
- Gay man
- Bisexual
- Other
- Prefer not to say

Do you consider yourself disabled?

Disability is defined in the Equality Act 2010 as “physical or mental impairment, which has a substantial and long term adverse effect on a person’s ability to carry out normal day to day activities”. Please tick one box.

- Yes
- No
- Prefer not to say

What is your age group?

Please tick one box

- 16 – 24 years
- 25 – 34 years
- 35 – 44 years
- 45 – 54 years
- 55 – 64 years
- 65 + years
- Prefer not to say

What is your ethnic group?

Choose the appropriate box to indicate your cultural background. Please tick one box.

White

- British
- Irish
- Gypsy or Irish traveller
- Other white background (please fill in the box at the end of this section)

Black or Black British

- Black Caribbean
- Black African
- Other black background (please fill in the box at the end of this section)

Mixed

- White and black Caribbean
- White and black African
- White and Asian
- Other mixed background (please fill in the box at the end of this section)

Asian or Asian British

- Indian
- Pakistani
- Bangladeshi

Other Asian background (please fill in the box at the end of this section)

Chinese or Chinese British

Chinese or Chinese British

Arab

Arab

Other

Prefer not to say

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

What is your religion?

Please tick one box

Buddhist

Christian

Hindu

Jewish

Muslim

Sikh

None

Prefer not to say

Other religion (please specify)

Meeting paper

Council on Thursday, 12 April 2018

Public business

Reviewing our publication and disclosure policy

Purpose

To update Council on the review of our publication and disclosure (P&D) policy.

Recommendations

The council is asked to note this paper.

1. Introduction

- 1.1. The current publication and disclosure policy is comprised of two parts:
 - i. The over-arching policy: this includes the legal framework and principles that guide publication and disclosure.
 - ii. A fitness to practise appendix: this explains how the policy applies to fitness to practise information, including the length of time that sanctions remain on the register.
- 1.2. The publication and disclosure policy is delegated to the Chief Executive and Registrar under the 'Scheme of Delegation'. The policy was first agreed in 2012, and a further minor change was made in 2014.
- 1.3. Whilst the policy is delegated to the Chief Executive and Registrar, we want to provide Council with assurance about our approach to reviewing the policy and provide an opportunity to share the principles that will underpin the policy to ensure they are sound.
- 1.4. The current policy requires updating due to the forthcoming General Data Protection Regulations (GDPR) which come in to effect in May 2018 and because of gaps that we have identified in the current policy, and areas that require further clarification. In addition, GDPR will require consultation on policies and systems that will potentially have a 'high impact' on individuals as part of the data protection impact assessment process.

2. Legal framework

- 2.1. We have taken the following legislation into account when reviewing the publication and disclosure policy:
- The Pharmacy Order 2010 and other relevant aspects of our rules;
 - The relevant provisions of other legislation, such as the Freedom of Information Act 2000, GDPR, Data Protection Act 1998 and the Human Rights Act 1998 and successor legislation;
 - The Medicines Act 1968

3. Publication and disclosure policy

- 3.1. We are in the process of finalising a review of the current publication and disclosure policy which has included a desk-based review of other similar policies.
- 3.2. We intend to consult on:
- An over-arching policy which sets out our principles for publication and disclosure, including what we mean by disclosure in the public interest.
 - Appendix 1 which sets out the information we publish, disclose routinely and disclose on a case by case basis about the pharmacy professionals we regulate.
- 3.3. At a later date, we intend to develop further appendices that explain what we publish and disclose in relation to registered pharmacies and pharmacy education.
- 3.4. The publication and disclosure policy and appendix 1 will be the subject of a ten-week consultation, beginning in Spring 2018.
- 3.5. After the consultation, we will develop a report of the responses received and make changes to the policy and appendix in light of the feedback. Once the policy has been agreed by the Chief Executive and Registrar, we will provide an update to Council.

4. Publication and disclosure policy principles

- 4.1. The draft publication and disclosure policy includes a number of principles that under-pin and inform the circumstances in which we will publish and disclose information. When making decisions on what information to publish or disclose we are committed to:

- being open and transparent about the processes we adopt and the decisions we make
 - ensuring that we comply with the legal duties placed upon us with regard to the protection of personal data and the common law duty of confidentiality
 - treating confidentially information that ought legitimately to be regarded as commercially sensitive (subject to FOI or other legal requirements)
 - ensuring that any disclosure of information is lawful and proportionate, and
 - publishing information in an easily accessible format where possible
- 4.2. In addition to publishing information, the new policy will address the disclosure of information to third parties. Where we are considering making a disclosure in the public interest (whether in relation to fitness to practise or other information), there will be a need to balance the public interest in favour of disclosure, with the individual's right to privacy under data protection and human rights legislation and the common law duty of confidentiality.

5. Equality and diversity implications

- 5.1. We have undertaken a partial equality impact assessment. This included assessing the implications of the policy against a series of characteristics (race, disability, sex, age, etc.) to ascertain if there is any impact on groups or individuals.
- 5.2. Given the potentially high impact on an individual's life, we will complete a full equality impact assessment during the review and consultation process.

6. Communications

- 6.1. The review of our P&D policy is part of an integrated programme of communications and engagement for four key activities happening from April-July, and includes the:
- Registered pharmacies consultation
 - commencement of PSIO order 2016 and update to standards for registered pharmacies
 - publication of new guidance for pharmacy owners on a safe and effective pharmacy team
 - publication and disclosure policy consultation

- 6.2. We plan to publish the consultation and draft policy on our website in May 2018. It will also be sent to the Information Commissioners Office and specific stakeholders to seek feedback. In particular, we will seek to engage with patient representative groups, and with members of the public through focus groups, in order to understand what information patients and the public expect should be published or disclosed.

7. Resource implications

- 7.1. The resource requirements for this work have been budgeted for.

8. Risk implications

- 8.1. Given the introduction of GDPR, and the length of time the policy has been in place, there are risks in failing to progress this work promptly. To mitigate any risk associated with the time taken to review and revise the P&D policy, we have added a note to the current policy stating that the policy and annex is being reviewed and we will be consulting in spring 2018. We have also added the restorations interim policy to the current policy as an addendum.

9. Monitoring and review

- 9.1. The P&D policy will be reviewed on a cycle of five years. However, given its importance and the range of areas it covers it will also be reviewed if there is a significant change to regulatory practice, approach or to the legislation.

Recommendations

The Council is asked to note this paper.

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General Pharmaceutical Council

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29 March 2018

Meeting paper

Council meeting on Thursday, 12 April 2018

Public business

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

Purpose

To set out how the GPhC provides assurance to the public that there are enough staff, suitably skilled and qualified, for the safe and effective provision of pharmacy services at registered premises.

Recommendations

The council is asked to:

- note the way we provide assurance to the public about whether pharmacy owners are meeting the standards for having sufficient staff at registered premises;
- note the new guidance we will provide for pharmacy owners; and
- note how our inspections assess whether there are sufficient staff and the action we take where staffing levels are insufficient.

1. Introduction

1.1. The standards for registered premises contain a requirement for there to be enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided. We assess this standard in all our routine inspections. Between 1 November 2013 and 26 March 2018, we inspected 14,460 registered pharmacies. Of these, 320 (2.2%) failed to meet the relevant standard for having enough staff, suitably qualified and skilled, for the safe and effective provision of the pharmacy services provided.

- 1.2. In all cases where the pharmacy failed to meet the standard, we required the pharmacy owner or superintendent pharmacist to make the necessary improvements by completing an action plan within a set timescale. 310 (96.9%) have done so to date with the remainder in the process of completing the improvements.
- 1.3. Our inspections have therefore indicated that the overwhelming majority of pharmacies (97.8%) have met the standard for having enough staff for the services they provide. However, we know from the feedback we have received from individual pharmacy professionals, from our consultations and crowdsourcing, from stakeholder organisations and from media investigations that there is a continuing concern about the pressures faced by the pharmacy team and strongly held views that staffing levels are not sufficient for the volume of work within individual pharmacies. As a result, we have continued to assess how, within our statutory remit, we can strengthen the assurance we need to provide for patients and members of the public.

2. Our approach to the question of setting minimum staffing levels

- 2.1. We take the clear view that setting the right staffing levels is best done by the people responsible for managing a pharmacy, rather than by the regulator at a distance. Where we come in is to take steps to ensure our standards are met in practice. This approach is similar to other healthcare regulators such as the Care Quality Commission and the Nursing and Midwifery Council, neither of which sets staffing levels for the professions they regulate. The staffing levels needed to provide safe and effective services will vary significantly between pharmacies depending on the services they provide, their experience, workloads and many other factors. Our role is to ensure that pharmacy owners have taken account of all relevant factors – including input and advice from responsible pharmacists - in developing staffing plans and to assess on the ground whether the staffing levels and the skills and qualifications of the pharmacy team are sufficient for safe and effective pharmacy practice.
- 2.2. There are over 14,000 registered pharmacies in Great Britain. Each has its own individual context, different volumes of dispensing, different services and different sets of skills and knowledge within the team. It would be impractical for the regulator at a distance to devise a model which addressed every variation across all registered pharmacies. In addition, pharmacies will be responding quickly to changing circumstances, including the introduction of technology such as robots, ongoing training and qualifications of staff, changing numbers of patients with different needs. These require a flexible approach and potential changes to staffing levels and mixes to meet patient needs. Again, this supports the view that setting staffing levels is best done by those responsible for managing a pharmacy.

3. How we are strengthening assurance for the public about whether pharmacy owners are meeting the standards for sufficient staffing levels.

3.1. We will do this through:

- new guidance for pharmacy owners which sets out clearly the actions that pharmacy owners must take to set staffing levels and ensure concerns can be raised and addressed; and
- a robust inspection approach which tests how this is implemented on the ground and requires owners to take action where standards are not met.

New guidance

3.2. Subject to Council approval, we will be publishing new guidance for pharmacy owners to promote safe and effective pharmacy teams. This follows the consultation last year on draft guidance and the analysis of responses which we presented to Council in March and which has now been published.

3.3. In light of the comments we received which highlighted concerns about staffing levels, we are currently revising the guidance to include more specific information on the responsibilities of owners. We will bring the revised guidance to Council in May and will include the following:

When setting staffing levels for each registered premises, pharmacy owners must:

- *Develop a staffing plan which takes account of the individual context of the pharmacy. This includes the volume of medicines dispensed; how and where medicines are supplied to patients; the population served by the pharmacy, including vulnerable patients; the range of services provided; the knowledge, skills and experience of the pharmacy team at the premises; previous incidents and errors and the reasons for them; and feedback from patients and members of the public*
- *Ensure each registered premises has a contingency plan for short and long-term staff absence, whether planned or unplanned*
- *Ensure that all members of the pharmacy team are aware of who they should contact within their individual pharmacy or wider organisation to raise concerns about staffing levels*

- *Ensure that all concerns raised by the pharmacy team about staffing levels at any registered premises are addressed and feedback is provided to the pharmacy team about how the concerns have been addressed*
- *Ensure the reasons for any dispensing errors are assessed and appropriate remedial action taken to learn from these, including action to change the number or skill mix of the pharmacy team where necessary.*

Inspections

Assessing staffing levels at registered pharmacies

- 3.4. To make an assessment about whether there is a sufficient number of qualified and skilled staff to provide safe pharmacy services, inspectors will continue to speak to the whole pharmacy team and will ask them a range of questions as well as observing activities in the pharmacy and checking relevant documentation.
- 3.5. In relation to staffing levels inspectors will continue to assess:
- Whether the staff numbers or structure has changed in recent months and, if so, what have been the consequences for services and patient safety?
 - Whether staff are performing roles in line with their skills, qualifications and competence (i.e. inspectors will usually ask what training they have completed and will pose scenarios as well as observing who is doing what in the dispensary)
 - Whether routine tasks are being completed (e.g. stock being put away neatly, date checking for out-of-date medicines etc.) and, if not, whether delays are due to inadequate staff numbers
 - Whether there are large queues of patients at the pharmacy and whether phone calls are left unanswered. If so, whether this is a regular occurrence

Taking action where staffing levels are insufficient

- 3.6. As now, we will take action to require any pharmacy that has not met the standard for having sufficient staff to make the necessary improvements quickly. We will do this by requiring owners and superintendents to complete an action plan with set timescales to show when the actions will be completed and who will be responsible for doing them. Owners and superintendents will need to make the improvements as soon as possible, especially where a risk to patient safety has been identified.

- 3.7. Once that action has been taken, the owner or superintendent pharmacist must notify us and we will check that the standards are now achieved. If they are, we will sign off the report and the action plan will be complete. If we do not agree that the standards are achieved the owner or superintendent must take further action to achieve the standards.

4. Equality and diversity implications

- 4.1. The guidance will apply to all pharmacy owners and all registered pharmacies will be covered by our inspections.

5. Communications

- 5.1. Subject to Council approval in May we will publish our guidance on a safe and effective pharmacy team shortly afterwards. We intend to publish inspection reports, subject to considering responses to our forthcoming consultation on registered pharmacies.

6. Resource implications

- 6.1. The guidance and our inspection approach form part of the budget agreed for 2018/19.

7. Risk implications

- 7.1. Producing new and more detailed guidance and reinforcing how our inspections provide assurance mitigates the risk that owners are unclear about their responsibilities and the risk that we are perceived as unable to take action where standards are not met.

8. Monitoring and review

- 8.1. We will continue to monitor how pharmacies are meeting standards through our inspections.

Recommendations

The council is asked to:

- note the way we provide assurance to the public about whether pharmacy owners are meeting the standards for sufficient staff;
- note the new guidance we will provide for pharmacy owners; and
- note how our inspections assess whether there are sufficient staff and the action we take where staffing levels are insufficient.

Mark Voce, Director of Education and Standards (Interim)

General Pharmaceutical Council

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