

Consultation on developing our approach to regulating registered pharmacies

May 2018



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About the GPhC

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

Our main work includes:

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

Foreword

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

Over the last five years we have made significant improvements to how we regulate registered pharmacies. We have heard that the changes we have made are welcome and are working well in practice. But we have also heard that there are opportunities to develop our approach further 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 changes we are seeing in how pharmacy services are delivered. We are increasingly noting 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 in the future.

So it is clear that a 'one-size-fits-all' approach to regulating and inspecting pharmacies will not work in the future. We plan to make our approach more flexible, agile and responsive.

We propose introducing new types of inspection 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, in our view, marks a significant moment of change. It will allow us to provide much more assurance to patients and the public, and to those working across pharmacy and health, that pharmacies are meeting standards that ensure the provision of safe and effective services. It will also shine a light on the outcomes of inspections, sharing examples of practice that everyone in pharmacy can use to learn and improve.

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



Overview

We are consulting until 9 August 2018 on developing our approach to regulating registered pharmacies.

This consultation asks for views on our proposals to further develop our approach to regulating registered pharmacies.

We are proposing the following key changes:

1. Introducing new types of inspection

We are planning to move to a new model that includes three types of inspection: routine inspections, intelligence-led inspections and themed inspections. This will help us to make sure 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. This will make sure the outcomes of the inspection reflect whether the pharmacy is meeting the standards every day.

3. Changing the inspection outcomes

We are proposing to change our present model for describing the outcomes of an inspection. There would be two possible outcomes for an inspection overall ('standards met' or 'standards not all met'), and four possible findings at the principle level ('standards not all met', 'standards met', 'good practice' and 'excellent practice').

4. Requiring all standards to be met to receive an overall 'standards met' outcome

If any standard was found not to be met, this would result in a 'standards not all met' outcome overall.

5. Publishing inspection reports

We are planning to publish inspection reports, and improvement action plans when relevant, on a new website. This will be designed so that the information is easy to search and analyse.

6. Sharing examples of notable practice

We will publish examples of notable practice that we identify through inspections in a 'knowledge hub' on the new website. This will help encourage continuous learning and improvement in pharmacy.

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.

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/registered-pharmacies 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

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 making decisions on how to develop our approach to regulating registered pharmacies, and on when the new approach will be implemented. We will also publish a summary of the responses and an explanation of the decisions taken on our website.

Background

In 2012, we set out **a new vision for the regulation of registered pharmacies in our consultation *Modernising pharmacy regulation***. We made clear our ambition for pharmacy regulation to move beyond a focus on legal compliance, checklists 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 was to create and maintain the right environment – both organisational and physical – for the safe and effective practice of pharmacy.

Following the introduction of these new ‘outcome-focused’ standards, we developed and implemented a new approach to inspection in 2013. This marked a significant change from the previous tick-box approach with its narrow focus on rules, 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. Inspectors also speak to all 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 people that use and receive pharmacy services.

Inspectors prepare reports for pharmacy owners and superintendents detailing the GPhC’s judgement of how well their pharmacy is meeting the standards.

If one or more standards are not being met the pharmacy must develop an improvement action plan, and we follow up with the pharmacy to make sure it makes the improvements needed within the time we set.

Evaluating our approach

In February 2015, we published **an update paper, *Modernising pharmacy regulation: from prototype to implementation***. This highlighted the progress that had been made to modernise pharmacy regulation, including through the new approach to inspection. It also highlighted the areas where we were planning to adapt and change our approach in the future, including changes to how inspections were rated. The paper committed us to consulting on proposed changes later, once there had been the necessary changes to the law (which we expect to come into effect soon).

We also commissioned in 2015 **an external evaluation, by ICF International**, of our approach to regulating community pharmacies. This concluded that our approach was seen to be working well. The study also highlighted some feedback for us to consider.

New legal powers

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 those on publication and enforcement.

The new legislation – **the Pharmacy (Premises Standards, Information Obligations etc) Order** – was agreed in 2016 and will come into effect in May 2018.

Ongoing engagement

Since 2015, we have continued to ask for feedback on our approach from stakeholders across pharmacy, as well as from 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.

We held focus groups with patients and the public in December 2017 to get 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. There was also overall support for our proposed approach.

We have used what we have heard from stakeholders and patients and the public – including from these focus groups – to develop the proposals in this consultation.

What we have learnt from inspections

Since we introduced the new ‘show and tell’ approach to inspections, we have inspected 12,825¹ registered pharmacies across Great Britain. We expect to have inspected every registered pharmacy in Great Britain by Summer 2018. 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 improvements needed.²

¹ From 1 November 2013 to 1 March 2018

² The remaining 1% is made up of plans where actions were not yet due, or where they had long lead times



Our strategic approach to regulating registered pharmacies

We believe that pharmacy regulation has a significant role to play in quality improvement – of which safety is a vital 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. For registered pharmacies, this means:

- providing assurance that the standards for registered pharmacies are being met, and
- driving continuous improvement in the quality of services and care for the public

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 different healthcare needs: some may have long-term conditions while others may visit a pharmacy far less often. The NHS contracts to which pharmacies work vary across England, Scotland and Wales, as does the way services are funded. And we know that technology, and the increased use of digital communications, will continue to influence the way services are provided in the future.

It is therefore vital 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. We believe that an outcome-focused approach is still the only way to do this.

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.

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. We will increasingly use information and intelligence to effectively target our resources where they can have the most impact. We know we are in a unique position because through our inspections we see many areas of notable practice in pharmacy. Therefore, publishing inspection reports and sharing what we learn from inspections is also central to our new approach and to helping us make sure patients and the public receive safe and effective care.

How we regulate registered pharmacies



There are several ways in which we regulate registered pharmacies:

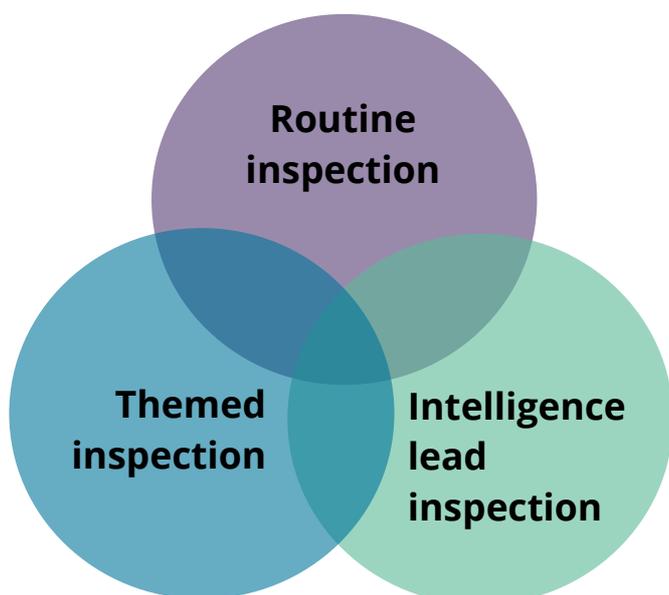
- a Through **registration** we are clear about the criteria a pharmacy must meet to be registered with us, and this includes demonstrating how the standards for registered pharmacies will be met.
- b We set **standards** for registered pharmacies, which make clear the expectations on owners of pharmacies and the outcomes that must be met to make sure 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 Through our **inspections** we provide assurance that the standards for registered pharmacies are being met. This process also plays an important part in making sure the quality of pharmacy services improves. (See section 1)
- d We will shortly have powers to **publish** inspection reports. Publication of inspection reports is an important way to provide assurance and drive improvement in the quality of pharmacy services. (See section 4)
- e We will have several **enforcement tools** that we can use to make sure that pharmacy services delivered at or from a registered pharmacy are safe and effective. (see the *Changes to our enforcement powers* section)
- 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

1. Introducing new types of inspection

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

Types of inspection



Routine inspections

- 1.2 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 make sure our programme of inspections is increasingly more flexible and effective and is based on indicators of risk when deciding which pharmacies should be inspected first.
- 1.3 This means that we will first inspect pharmacies previously rated as 'poor', followed by those rated as 'satisfactory with an action plan'. Once we have inspected pharmacies which have 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 allow us to evaluate whether previous improvements have been sustained.
- 1.4 There will be other indicators that we will also use when deciding 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.
- 1.5 As is the case now, if one or more of the standards are not met, the pharmacy owner will have to develop an

improvement action plan setting out what they will do, within a set time, to put right the issues and meet the standards for registered pharmacies. We will continue to follow up with these pharmacies to make sure they make the improvements needed and that the standards are fully met.

Intelligence-led inspections

- 1.6 We often receive information about pharmacies from other people or organisations, including regulators, healthcare professionals and the public, as well as from journalists and the media. We already use this 'intelligence' 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.
- 1.7 We will use some of our existing resources to make sure we can be more responsive and are able to rapidly deal with risks or concerns raised with us.
- 1.8 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 help us prioritise our future routine inspections.

Themed inspections

- 1.9 We plan to carry out a programme of themed inspections. These will involve visiting a selection of pharmacies to focus on specific themes or issues in more depth. These could be, for example, risk management in supplying medicines online, or services provided to a care home.
- 1.10 We may also carry out themed inspections as a result of the issues and risks identified by our routine and intelligence-led inspections. These inspections will be flexible and allow us to respond to emerging risks and future developments in the provision of pharmacy services. They will allow us to better understand the underlying issues, and their causes and effects.
- 1.11 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.
- 1.12 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
 - allowing other pharmacy owners to learn and to improve the quality of the services they provide

We will also use what we learn from these inspections to develop our own regulatory work, and to develop guidance.

Questions about these proposals

Do you think the three types of inspection will:

- provide more assurance that pharmacies are meeting our standards?
- enable us to be more agile and responsive to risks or changes in pharmacy or healthcare?
- help to drive improvements through identifying and sharing good practice?

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

2. Unannounced inspections

- 2.1 At the moment, we write to pharmacy owners ahead 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. This gives additional assurance that the outcomes of an inspection more accurately reflect the experience of patients and the public, and how well a pharmacy is meeting our regulatory standards day to day.
- 2.2 Taking part in an inspection can take members of the pharmacy team away from providing services to patients for short periods. We realise that pharmacy owners and superintendent pharmacists may therefore want advance notice of when an inspection would take place, so they can consider whether they need to have extra staff available to continue to provide services safely and effectively. However, we want to emphasise that if our inspectors think that continuing an inspection may mean that patient safety may be put at risk, they will leave and come back at another time, as they do now.
- 2.3 We realise that pharmacy owners and superintendent pharmacists may also want to be there during an inspection. But we want to make sure that an inspection will reflect the experience patients and the public have on that particular day. And the pharmacy should be meeting the standards every day.

- 2.4 We are therefore proposing that inspections will be unannounced as a general rule. However, we know there may be situations when it is not possible for us to inspect a pharmacy unannounced: for example, if a registered pharmacy is in a prison or other secure environment. Likewise, we believe that themed inspections, which look at specific issues involving a number of pharmacies and a team of inspectors, will need to be arranged in advance.
- 2.5 Our inspectors always make sure that, by their presence, they are not increasing risks to patients.

Questions about these proposals

Do you think that moving from announced to unannounced inspections as a general rule provide greater assurance that pharmacies are meeting our standards every day?

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

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

3. Changes to the inspection outcomes

- 3.1 Under our present system, pharmacies get an overall outcome from their inspection which may be 'poor', 'satisfactory', 'good' or 'excellent'.
- 3.2 We know from the ICF research we commissioned, and the feedback we received, that there were concerns about the way we described the outcomes. In particular: a lack of clarity and differentiation between these outcomes, and the term 'satisfactory'. The research suggested two possible solutions. One solution was to introduce a scoring system with more grades. The other solution was to introduce a simpler 'pass or fail' outcome which had limited scope for misinterpretation.
- 3.3 We want to make sure the overall outcome of an inspection makes clear to patients, the public and pharmacy owners whether a pharmacy has met, or not met, the standards. Our suggested approach to the overall outcome is:
 - Standards met, or
 - Standards not all met
- 3.4 When a pharmacy has not met one or more standards, we would make clear in the inspection report whether an improvement action plan is in place, or whether enforcement action is being taken. Following are examples of how the outcomes would be presented in an inspection report.



<p>Outcome of inspection</p> <p>The overall outcome of a pharmacy inspection can be 'standards met' (all the standards are met) or 'standards not all met' (one or more of the standards below are not met)</p>	<p>✓ Standards met</p>
<p>Outcome of inspection</p> <p>The overall outcome of a pharmacy inspection can be 'standards met' (all the standards are met) or 'standards not all met' (one or more of the standards below are not met)</p>	<p>✗ Standards not all met</p> <p>Improvement action plan in place</p>
<p>Outcome of inspection</p> <p>The overall outcome of a pharmacy inspection can be 'standards met' (all the standards are met) or 'standards not all met' (one or more of the standards below are not met)</p>	<p>✗ Standards not all met</p> <p>Enforcement action underway</p>

3.5 We believe that this approach will provide clear, simple assurance, rather than introducing more grades with more opportunities for ambiguity. We tested this approach with patient and public focus groups in 2017, and there was broad agreement that these outcomes were clear and simple to understand.

3.6 We will also continue to provide a finding for each of the five principles in the standards for registered pharmacies, because this provides us, owners, and their teams with a way to measure their performance. This will help us all to understand on which standards pharmacy owners need extra guidance and support, and will also help to identify those standards where pharmacy owners perform well. We believe this approach supports and drives continuous improvement in the quality of pharmacy services for patients and the public.

3.7 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 all met**
- **standards met**
- **good practice, and**
- **excellent practice**

3.8 Under our proposed new approach, a pharmacy must meet all the standards for registered pharmacies to get an overall outcome of 'standards met'. If a pharmacy has not met a standard, this would result in a 'standards not all met' rating overall. This is because the standards have been in place for five years. Patients expect that if a pharmacy receives a 'standards met' outcome they have met all the standards.

3.9 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. 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.

3.10 If a pharmacy does not meet the standards this will mean that the pharmacy owner has 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 make sure the standards that have not been met initially will subsequently be met. Importantly, it includes a date by which the improvements will be made. Improvement action plans have been found to be an effective tool in making sure the necessary improvements are made. Through the ICF research we also heard that developing improvement action plans also helped pharmacy professionals focus on the issues of most importance to patients.

3.11 Once the pharmacy owner has told us they have completed the improvement action plan, the inspector may need to re-visit the pharmacy to review whether the necessary improvements have been made. Once the inspector is satisfied that the pharmacy is meeting the standards and that the improvements are being

sustained, we will tell the pharmacy owner that the improvement action plan has been completed and that there will be no statutory enforcement action. We will send an updated overall outcome and report to the pharmacy. We will also publish the updated outcome and report on our website. The previous inspection report will be stored in a section showing previous inspection history.

Example 1 Record keeping – standard 1.6

On looking through the private prescription record book the inspector sees that in the previous few months there are four records which are incomplete, with either the date of the prescription, the prescriber’s address or the quantity of medicine left out.

In general, apart from these exceptions, record keeping within the pharmacy appeared to be up to date and complete.

These findings show very minor non-compliance in a limited number of instances that are unlikely to affect patient safety or patient care. In these circumstances the relevant standard is still judged to be met.

Example 2

Confidentiality – standards 1.7, 5.3

During an inspection the inspector finds a pharmacy does not take the necessary measures to ensure that patient information is kept confidential.

While in the pharmacy the inspector sees that confidential information, including Medicines Use Review forms, is left on the consultation room desk with the door left wide open and the room left unattended. All the prescriptions ready for collection are stored in a place where the patient details are visible to other patients and customers of the pharmacy.

It is also confirmed by members of the pharmacy team that there has not been any staff training on keeping information confidential for many years.

These findings show multiple instances of non-compliance in relation to keeping patient information confidential and so the standards concerned with confidentiality will be found to be not met.

Questions about these proposals

We propose having two possible overall outcomes from an inspection - 'standards met' and 'standards not all met'. Do you think this will make it clear to patients, the public and pharmacy owners that a pharmacy has met, or not met, the standards?

We propose having four possible findings for each of the principles - 'standards not all met', 'standards met', 'good practice' and 'excellent practice'. Do you think this will:

- provide owners, their teams and the GPhC with a way of measuring performance?
- continue to drive improvement?

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

Do you have any comments about the proposed wording of the overall outcome of an inspection, that is 'standards met' or 'standards not all met'?

Do you have any other comments on the changes we are proposing to the outcome of an inspection?

4. Publication

4.1 We have stated publicly that we intended to publish all inspection reports once we were given the legislative powers to do so. There was widespread agreement in the ICF research that inspection reports help pharmacy owners to improve the services provided to patients and the public. And we believe publishing inspection reports will empower patients, the public and pharmacy. Publishing inspection reports is necessary for four main reasons:

- We should be open and transparent about not only the outcome of an inspection, but also the evidence we have gathered to come to that decision.
- Publishing inspection reports will provide clear assurance to the public that pharmacies have met the standards for registered pharmacies.
- Publication will allow the pharmacy sector as a whole to use the information in the reports to improve.
- Publishing inspection reports will bring us into line with the approach taken in other healthcare services.

Inspection reports

4.2 We will publish all inspection reports following a routine or intelligence-led inspection in the future. Inspection reports will not contain commercially sensitive information or personal identifiable information about patients or the pharmacy team. An inspection report will

include a summary report that will contain a link to the detailed report. The detailed report will contain the evidence of what was found and examples of notable practice. You can see **examples of a summary report with standards met, a summary report with standards not met, and a detailed inspection report** on our website.

4.3 We will also publish all improvement action plans. These explain the actions the pharmacy owner will take to make sure they meet the standards for registered pharmacies.

4.4 The summary report will be the main source of information that the public will see on the website. It will be a clear and accessible version of the detailed report. It will contain a summary of the overall outcome, the findings at principle level and links to any improvement action plan.

4.5 The detailed report will contain the evidence that supports the overall outcome and the findings at principle level. The main audience for the detailed report will be the pharmacy owner, superintendent and the pharmacy team. The detailed report will be available to the public through a link on the summary report.

4.6 To produce our proposals we have used 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.

- 4.7 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 there should be a link in the summary report to the more detailed report. It was also suggested by participants in the focus groups that there should be a link to any improvement action plans, with timelines for the improvements to be made, in both the summary and detailed reports.
- 4.8 The reports we publish following a themed inspection will not include individual outcomes for the registered pharmacies involved. This type of inspection looks at specific issues in the way a pharmacy works or aspects of services it provides. We will produce one overall report for each themed inspection, and they will be published on the website. These reports will be interactive and engaging, with the information easily accessible as a source of learning for pharmacy as a whole.
- 4.9 There was a clear consensus among participants in 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. While we do not have powers to make pharmacy owners display the outcome of an inspection, we plan to look at options for supplying pharmacies with a sign showing

the inspection outcome. This would tell people using that pharmacy whether the pharmacy met our standards during its last inspection.

Questions about these proposals

Do you think we should publish inspection reports?

Do you think publishing inspection reports will:

- 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?

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 so that we are open and transparent about all aspects of our inspection process.

Do you think we should publish improvement action plans?

Do you think pharmacy owners should be expected to display the inspection outcome in the pharmacy?

5. The website and knowledge hub

- 5.1 We want the publication of inspection reports to drive improvements in the quality of pharmacy services and care. This will only happen if we publish inspection reports in a way that is accessible and lets people easily find and analyse information they can use to learn and improve.
- 5.2 We are designing a new website that will host our published inspection reports. We are focusing on ease of accessibility, equality principles and the user experience. We expect the inspection reports to be searchable by post code, pharmacy name, type of pharmacy, inspection outcomes, by principle, by standards, by using a map or by 'recently published'.
- 5.3 The summary report will be the main source of information on the website. It will contain a summary of the overall outcome, the findings at principle level and links to the detailed report and any improvement action plan. The detailed report will contain the evidence that supports the overall outcome and the findings at principle level. It also identifies areas of notable practice – both good and excellent practice – as well as examples where standards are not all being met.
- 5.4 We will use these areas of notable practice to create case studies from which others may learn. These will sit within an online 'knowledge hub'. We intend the hub to be a rich source of learning, mainly for the sector, over time. The site will be interactive and searchable on a self-service

basis. Finally, we will also publish inspection reports alongside the pharmacy's entry on the online register.

Questions about these proposals

Do you think the interactive website and knowledge hub will:

- make information easily accessible?
- encourage the sharing of knowledge within the pharmacy sector?
- enable learning from examples of standards not all being met, and of good and excellent practice?
- drive improvements within pharmacy?

6. Publishing inspection reports

6.1 It is important that we publish all inspection reports as soon as we can after each inspection. We believe that unnecessary delays will undermine the assurance 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
- make sure that every inspection report is quality assured

As part of our new proposals we will:

- update our decision-making framework
- develop a process for reviewing the overall outcome of an inspection, if a pharmacy owner challenges our decision-making on the grounds of factual accuracy. The process will involve an inspection team manager who is independent of the region in which the pharmacy is located
- notify the pharmacy owner before the publication of the inspection report

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

If a pharmacy has not met all of the standards, we will publish the inspection report in the usual way. Once the inspector is satisfied that the improvement action plan has been completed, that the pharmacy is meeting the standards and that the improvements are being sustained, we would then publish on our website an updated overall outcome and report showing that the pharmacy has met all the standards. However, the previous inspection report would still be available in a section showing previous inspection history.

6.3 The nature of themed inspections (which may involve an inspection of a significant number of pharmacies by more than one organisation) means that these reports will necessarily take longer to prepare and quality assure. These reports will also be published on our website.

Question about these proposals

Do you have any comments about the publication process?

7. Impact of the proposals

Overall questions about these proposals

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

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

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

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
- Sexual orientation.

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

Please describe the impact and the individuals or groups concerned.

Changes to our enforcement powers

The Pharmacy (Premises Standards, Information Obligations etc) Order 2016

brings about a number of changes to our enforcement powers for pharmacies failing to meet the standards for registered pharmacies.

If a pharmacy is found to not be meeting the standards for registered pharmacies there are a number of actions we can take as the regulator. Some of these are statutory ones. We may:

- require pharmacy owners to complete an improvement action plan
- impose conditions on specific pharmacy premises when this is necessary to secure the safe and effective practice of pharmacy
- serve an improvement notice for a failure to keep to conditions relating to the standards for registered pharmacies, or a failure to meet the standards
- impose interim measures against pharmacy owners – these decisions are made by the Fitness to Practise Committee
- disqualify a pharmacy owner or remove one or more entries to the register if the Fitness to Practise Committee are satisfied that the pharmacy owner is unfit to carry on the relevant business safely and effectively

Our proposed approach to enforcement

We will be developing an enforcement policy that will set out how we use our enforcement powers, and we will be asking for views on any future guidance for our statutory committees on decision-making. We have set out below some of the principles that will guide our approach.

We will:

- make decisions about when to use our enforcement powers consistently and proportionately, so that we take only the steps we need to take to make sure a pharmacy meets the standards and to safeguard patients and the public
- use our statutory enforcement powers only in situations when a pharmacy owner does not complete an improvement action plan and carry out the necessary changes to make sure our standards are met, or in situations when there is a serious risk to patient safety
- continue to work with other enforcement agencies and, when another organisation may be best placed to manage the concerns, refer the matter to it
- publish information about the enforcement action we have taken, when this is appropriate and allowed by law

Our future work

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

- review our standards for registered pharmacies to make sure they continue to prioritise patient care and the provision of safe and effective care. We know that the Department of Health and Social Care intends to ask for views on their giving the pharmacy regulators in the UK the power to set standards for superintendent pharmacists. We will wait for 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
- develop an enforcement policy that will set out how we will use our enforcement powers, and ask for views on any future guidance for our statutory committees on decision-making
- ask for views on the information we collect about registered pharmacies – at the point of registration, at renewal and day to day – to improve the way we regulate registered pharmacies
- ask for views on a new appendix to our publication and disclosure policy. This will cover the information we publish and disclose about registered

pharmacies, and will include how long reports remain on our website

- publish a report of what we have learnt from our inspections, including sharing examples of notable practice. This will include examples of good and excellent practice as well as examples of practice that falls below the expected standard. We will also explore the publication of an annual overview report
- so that we continue to use our resources effectively, consider whether we should continue to inspect all pharmacies on a rolling basis. It may be that other options, such as inspecting a sample 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 makes. If our Council approves, we expect to start publishing inspection reports in the first part of 2019.



Responding to the consultation

How we will use your responses

After the consultation, we will publish a report summarising what we heard.

If you respond as a private individual, we will not use your name or publish individuals' responses. 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.

We may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

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.

Under data protection law, you may ask for a copy of your response to this consultation or other information we hold about you, you may also ask us to delete your response. For more information about your rights and who to contact please [read our privacy policy](#) on our website.

Response to the consultation on developing our approach to regulating registered pharmacies

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:

email:

2. Where do you live?

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

3. Are you responding as:

- a pharmacist (please go to **Q4**)
 - a pharmacy technician (please go to **Q5**)
 - a pharmacy owner who is not registered as a pharmacist or pharmacy technician (please go to **Q6**)
 - a member of the pharmacy team who is not registered with the GPhC (please go to **Q7**)
 - a member of the public (please go to the consultation questions)
 - other (please give details below and then go to Q8)
-

4. Are you a superintendent pharmacist?

- Yes
- No

5. Are you a pharmacy owner?

- Yes
- No (please go to **Q7**)

6. Which of the following best describes the pharmacy that you own?

- Sole trader (please go to **Q8**)
- Partnership (please go to **Q8**)
- Body corporate (please go to **Q8**)

7. Do you work in a registered pharmacy?

- Yes
- No



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

- Community pharmacy (please go to **Q9**)
 - Hospital pharmacy
 - Primary care organisation
 - Pharmacy education and training
 - Pharmaceutical industry
 - Other (please give details)
-

9. Which of the following best describes the community pharmacy that you own or work in?

- An independent pharmacy or pharmacy chain (1-5 pharmacies)
- A small multiple pharmacy chain (6-20 pharmacies)
- A large multiple pharmacy chain (21 or more pharmacies)

Section B – Responding on behalf of an organisation

Please tell us your:

name: _____

job title: _____

organisation: _____

address: _____

email: _____

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

Please keep parts of my organisation’s response confidential

Please explain which parts you would wish to keep confidential.

1. Are you responding on behalf of a registered pharmacy?

Yes (please go to **Q2**)

No (please go to **Q3**)

2. Please choose the option below which best describes the pharmacy you represent.

Community pharmacy (please go to **Q4**)

Hospital pharmacy (please go to the consultation questions)

Primary care organisation (please go to the consultation questions)

Other (please give details)

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

Organisation representing patients and the public

Organisation representing pharmacy professionals or the pharmacy sector

NHS organisation or group

Research, education or training organisation

- 
- Government department or organisation
 - Regulatory body
 - Other (please give details)
-

4. Which of the following best describes the community pharmacy that you own or work in?

- An independent pharmacy or pharmacy chain (1-5 pharmacies)
- A small multiple pharmacy chain (6-20 pharmacies)
- A large multiple pharmacy chain (21 or more pharmacies)

Consultation questions

We are particularly interested in your views on the following points, although we welcome your comments on any issues that you want to raise about our proposed approach to regulating registered pharmacies.

Section 1: Introducing new types of inspection

In the *Introducing new types of inspection* section, we describe the changes we plan to make to the types of inspections we carry out.

1. Do you think the three types of inspection (routine, themed and intelligence-led) will:
 - provide more assurance that pharmacies are meeting our standards?
 Yes
 No
 Don't know
 - enable us to be more agile and responsive to risks or changes in pharmacy or healthcare?
 Yes
 No
 Don't know
 - help to drive improvements through identifying and sharing good practice?
 Yes
 No
 Don't know

Please give comments explaining your responses.

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



Section 2: Unannounced inspections

In the *Unannounced inspections* section, we describe our plans to move from announced to unannounced inspections as a general rule for routine and intelligence-led inspections.

3. Do you think that moving from announced to unannounced inspections as a general rule will provide more assurance that pharmacies are meeting our standards every day?

- Yes
- No
- Don't know

Please give comments explaining your response.

4. 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

5. Please describe the other instances we should consider.

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

Section 3: Changes to the outcomes of an inspection

In the *Changes to the inspection outcomes* section of the consultation document we describe the changes we plan to make to the outcomes of an inspection.

7. We propose having two possible overall outcomes from an inspection - 'standards met' and 'standards not all met'. Do you think this will make it clear to patients, the public and pharmacy owners that a pharmacy has met, or not met, the standards?
- Yes
 - No
 - Don't know

Please give comments explaining your response.

8. We propose having four possible findings for each of the principles - 'standards not all met', 'standards met', 'good practice' and 'excellent practice'. Do you think this will:
- provide owners, their teams and the GPhC with a way of measuring performance?
 - Yes
 - No
 - Don't know
 - continue to drive improvement?
 - Yes
 - No
 - Don't know

Please give comments explaining your responses.



Patients have told us that a pharmacy should meet all the standards to receive a 'standards met' outcome. This means that not meeting one standard would result in the pharmacy receiving an overall outcome of 'standards not all met'.

9. Do you think that not meeting one standard should result in the pharmacy receiving an overall outcome of 'standards not all met'?
- Yes
 - No
 - Don't know

Please give comments explaining your response.

10. Do you have any comments about the proposed wording of the overall outcome of an inspection, that is 'standards met' or 'standards not all met'?

11. Do you have any other comments on the changes we are proposing to the outcomes of an inspection?

Section 4: Publication

In the *Publication* section we describe our plans to publish individual inspection reports for routine and intelligence-led inspections and a composite report for themed inspections.

12. Do you think we should publish inspection reports?
- Yes
 - No
 - Don't know

Please give comments explaining your response.

13. Do you think publishing inspection reports will:

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

Please give comments explaining your responses.

14. Do you have any suggestions about the intended format and content of the summary and detailed inspection reports? You can see samples of the new report templates on our website.

15. Do you think we should publish improvement action plans?

- Yes
- No
- Don't know

Please give comments explaining your response.



16. Do you think pharmacy owners should be expected to display the inspection outcome in the pharmacy?

- Yes
- No
- Don't know

Please give comments explaining your response.

Section 5: The website and knowledge hub

In the *Website and knowledge hub* section of the consultation document we describe our plans to publish the reports on an interactive website and to introduce a knowledge hub for highlighting and sharing examples of standards not being met and of good and excellent practice.

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

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

Please give comments explaining your responses.

Section 6: Publication process

In the *Publishing inspection reports* section, we describe the process we will follow when quality assuring and publishing inspection reports.

18. Do you have any comments about the publication process?

Section 7: Impact of the proposals

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

- Positive impact
- Negative impact
- Both positive and negative impact
- No impact
- Don't know

Please give comments explaining your response.

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

- Positive impact
- Negative impact
- Both positive and negative impact
- No impact
- Don't know



Please give comments explaining your response.

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

- Positive impact
- Negative impact
- Both positive and negative impact
- No impact
- Don't know

Please give 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**
- Sexual orientation**

22. Do you think anything in the proposed changes would have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above?

- Yes
- No
- Don't know

Please give comments explaining your response.

23. Do you think there will be any other impact of our proposals which you have not already mentioned?

- Yes
- No
- Don't know

Section 8: Receiving updates

We would like to email you to update you about progress on this consultation as well as the 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 about the consultation on developing the approach to regulating registered pharmacies
- I would like to be contacted with news and information about other consultations from the GPhC

Please provide an email address for updates and communications from the GPhC. You can unsubscribe from our mailing list at any time by clicking on the 'unsubscribe' option within the email.

Equality monitoring

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

We want to make sure everyone has an opportunity to respond to our consultation on 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
- Prefer not to say

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 (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
- Other (please give more information in the box below)
- Prefer not to say



Appendix A: Collated consultation questions

In the *Introducing new types of inspection* section, we describe the changes we plan to make to the types of inspections we carry out.

1. Do you think the three types of inspection (routine, themed and intelligence-led) will:
 - provide more assurance that pharmacies are meeting our standards?
 - enable us to be more agile and responsive to risks or changes in pharmacy or healthcare?
 - help to drive improvements through identifying and sharing good practice?

Please indicate 'Yes', 'No' or 'Don't know' to the questions.

Please give comments explaining your responses.

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

In the *Unannounced inspections* section, we describe our plans to move from announced to unannounced inspections as a general rule for routine and intelligence-led inspections.

3. Do you think that moving from announced to unannounced inspections as a general rule will provide more assurance that pharmacies are meeting our standards every day?

Please indicate 'Yes', 'No' or 'Don't know'.

Please give comments explaining your response.

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

Please indicate 'Yes', 'No' or 'Don't know'.

5. Please describe the other instances we should consider.
6. Do you have any other comments on us carrying out unannounced inspections as a general rule?

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Please indicate 'Yes', 'No' or 'Don't know'.

Please give comments explaining your response.

8. We propose having four possible findings for each of the principles - 'standards not all met', 'standards met', 'good practice' and 'excellent practice'. Do you think this will:

- provide owners, their teams and the GPhC with a way of measuring performance?
- continue to drive improvement?

Please indicate 'Yes', 'No' or 'Don't know' to the questions.

Please give comments explaining your responses.

Patients have told us that a pharmacy should meet all the standards to receive a 'standards met' outcome. This means that not meeting one standard would result in the pharmacy receiving an overall outcome of 'standards not all met'.

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Please give comments explaining your response.

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12. Do you think we should publish inspection reports?

Please indicate 'Yes', 'No' or 'Don't know'.

Please give comments explaining your response.

13. Do you think publishing inspection reports will:

- provide greater transparency about the outcome of an inspection?
- provide 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 indicate 'Yes', 'No' or 'Don't know' to the questions.

Please give comments explaining your responses.

14. Do you have any suggestions about the intended format and content of the summary and detailed inspection reports? You can see samples of the new report templates on our website.

15. Do you think we should publish improvement action plans?

Please indicate 'Yes', 'No' or 'Don't know'.

Please give comments explaining your response.

16. Do you think pharmacy owners should be expected to display the inspection outcome in the pharmacy?

Please indicate 'Yes', 'No' or 'Don't know'.

Please give comments explaining your response.

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

- make information easily accessible?
- encourage the sharing of knowledge within the pharmacy sector?
- enable learning from examples of standards not being met, and of good and excellent practice?
- drive improvements within pharmacy?

Please indicate 'Yes', 'No' or 'Don't know' to the questions.

Please give comments explaining your responses.

In the *Publishing inspection reports* section, we describe the process we will follow when quality assuring and publishing inspection reports.

18. Do you have any comments about the publication process?

Please give comments explaining your response.

Overall questions about these proposals

19. What kind of impact do you think the proposals will people using pharmacy services?

Please indicate 'positive impact', 'negative impact', 'both positive and negative impact', 'no impact', or 'don't know'.

Please give comments explaining your response.

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

Please indicate 'positive impact', 'negative impact', 'both positive and negative impact', 'no impact', or 'don't know'.

Please give comments explaining your response.

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

Please give 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:

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Disability

Gender reassignment

Marriage and civil partnership

Pregnancy and maternity

Race

Religion or belief

Sex

Sexual orientation

22. Do you think anything in the proposed changes would have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above?

Please indicate 'positive impact', 'negative impact', 'both positive and negative impact', 'no impact', or 'don't know'.

Please give comments explaining your response.

23. Do you think there will be any other impact of our proposals which you have not already mentioned?



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