



Evaluating the GPhC's approach to regulating community pharmacies

Detailed Annexes

ICF Consulting Services

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Annex 1 Bibliography

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Annex 2 Linking the evaluation questions and sources of evidence and analysis

Table A2.1 Mapping the research tools to the evaluation questions and study objectives

Study objectives	Associated evaluation questions	Reference to research tools
Consistency in regulatory approach and alignment with GPhC's wider objectives		
I. Assess how far enforcement activities are more targeted, risk-based and outcome-focused	a) To what extent is the GPhC achieving its goal to create an approach to inspection that focuses on outcomes, drives improvement and is applied consistently by inspectors?	Depth interviews with inspectors and stakeholder organisations: <ul style="list-style-type: none"> ❖ <i>How far does the [GPhC's] approach focus on outcomes, drive improvement and is applied consistently by the inspectors?</i> ❖ <i>How helpful is the GPhC's inspection decision-making framework when thinking about inspections?</i>
II. Assess whether the new approach to regulation is applied consistently by inspectors and in line with the GPhC's wider ambitions and objectives	b) How do pharmacies prepare for inspections? c) How do pharmacies experience inspection? d) Do pharmacies use the GPhC's standards and other information available on the [GPhC] website? e) Do pharmacies consult information provided, for example, by the Royal Pharmaceutical Society or National Pharmacy Association?	Depth interviews with inspectors and stakeholder organisations: <ul style="list-style-type: none"> ❖ <i>How do pharmacies experience inspections (e.g. how do pharmacies prepare for inspection; is advance notification helpful)?</i> Depth interviews with community pharmacy professionals: <ul style="list-style-type: none"> ❖ <i>How did you prepare for your most recent inspection?</i> ❖ <i>Were there any costs involved in preparing for inspections (including time costs)? If you were to assess GPhC inspections against other inspections you've experienced so far from other regulatory bodies, would you say that GPhC inspections place a higher or lower burden on time and financial resources?</i>
Effectiveness of the new interventions		
I. Assess how far each newly-introduced intervention works as intended and the effectiveness of the overall regulatory approach in practice	a) Do the current standards set out clearly what a pharmacy needs to do to deliver effective patient care? b) What are the levels of awareness of the standards among pharmacies, and does this level of awareness change as a result of inspection? c) Does the level of awareness of the standards change as a result of inspection? d) Do pharmacies actively engage in trying to meet the standards, or are	Online census: <ul style="list-style-type: none"> ❖ <i>How would you describe your level of awareness of the GPhC's Standards for registered pharmacies?</i> ❖ <i>Please indicate for each of the following principles the degree to which you understand and have implemented the standards.</i> ❖ <i>Please indicate for each of the following outcomes the degree to which you consider you have understood and implemented the relevant standards</i> ❖ <i>How important would you say that inspection is for encouraging you to focus on patients and users of your service?</i>

	they merely seen as a reference tool for inspections?	❖ <i>Thinking about inspections, please indicate what information and guidance you find helpful?</i>
II. Assess how far each of the elements of the new approach interact as part of the “pharmacy journey” to help deliver better outcomes for patients/customers	<p>e) Which elements of an inspection – involvement of the whole pharmacy team, facilitating learning and good practice, collecting and agreeing evidence – seem most important in supporting pharmacies to meet the standards and to improve?</p> <p>f) Are the right areas being addressed within action plans, to ensure a focus on improving quality, including safety?</p>	<p>Online census:</p> <ul style="list-style-type: none"> ❖ <i>Please indicate the elements of inspection that are most important for meeting and further improving standard?</i> ❖ <i>Has your level of awareness of the GPhC's standards improved as a result of your inspection?</i> ❖ <i>What were the main areas highlighted in your action plan?</i> ❖ <i>Please indicate how helpful you find elements of action planning to be in improving standards of patient care at your pharmacy</i> ❖ <i>Thinking about the provision of inspection reports and ratings, please rate the degree to which you agree with the following statements</i> <p>Depth interviews with inspectors and stakeholder organisations:</p> <ul style="list-style-type: none"> ❖ <i>Which elements of an inspection – involvement of the whole pharmacy team, facilitating learning and good practice, collecting and agreeing evidence – seem most important in supporting pharmacies to meet the standards and to improve?</i> ❖ <i>Does the level of awareness of standards change as a result of inspections?</i> ❖ <i>Where an action plan is needed, are the right areas being highlighted in inspection reports, to ensure a focus on improving quality, including safety?</i> <p>Depth interviews with community pharmacy professionals:</p> <ul style="list-style-type: none"> ❖ <i>How did you prepare for your most recent inspection?</i> ❖ <i>Were there any costs involved in preparing for inspections (excluding having to meet an action plan if relevant)? Would you be able to quantify? Were these significantly different from what you have incurred from past inspections?</i> ❖ <i>You mentioned that you've spent about XXX [INSERT ANSWER FROM SURVEY – Q25] of your staff's time dealing with your most recent inspection. Is that correct? Would you say that this is roughly the same amount of time you've always spent on inspections? Would you say the new approach constitutes a greater or a lesser time burden than the previous approach? Why?</i> ❖ <i>If you were to assess GPhC inspections against other inspections you've experienced so far from other regulatory</i>

		<i>bodies, would you say that GPhC inspections place a higher or lower burden on time and financial resources? Or are they all about the same?</i>
Impacts/anticipated impacts on pharmacy and patient outcomes		
I. Test whether community pharmacies and their customers are experiencing the outcomes encouraged by the GPhC	<p>a) Do the standards encourage pharmacies to focus on patients and users of their services?</p> <p>b) Have the standards helped change a culture which previously focused primarily on rules and compliance, towards outcomes, innovation and improvement?</p> <p>c) What is the impact on pharmacies after inspection, particularly for those without action plans? Does it provide a continuing focus for improvement?</p> <p>d) Is action planning an effective intervention leading to sustained improvement?</p> <p>e) Does the provision of inspection reports and ratings provide an incentive for continued focus on quality provision of pharmacy services and improvement?</p>	<p>Online census</p> <ul style="list-style-type: none"> ❖ <i>Do you think that the standards encourage you to increase your focus on patients and users of your services?</i> ❖ <i>How important are standards in helping you focus on patients and users of your services. Please indicate the degree to which you agree to the following statements.</i> ❖ <i>How important would you say that inspection is for encouraging you to focus on patients and users of your service?</i> ❖ <i>Are there instances where your pharmacy practices go beyond the level required by the standards?</i> ❖ <i>The GPhC is planning to publish inspection reports and ratings (subject to the necessary legal powers). Do you think this will have any added value for pharmacies and patients?</i> ❖ <i>How do you think publishing inspection reports and ratings could impact on pharmacies and patients? Please state the degree to which you agree with the following statements.</i> <p>Depth interviews with inspectors and stakeholder organisations:</p> <ul style="list-style-type: none"> ❖ <i>Do the standards encourage pharmacies to focus on patients and users of their services? If so, how?</i> ❖ <i>Have the standards helped change a culture which previously focused primarily on rules and compliance, towards outcomes, professional decision making and improvement?</i> ❖ <i>Are there any unintended consequences of introducing the new outcome focused standards for pharmacy premises?</i> ❖ <i>Do inspections help pharmacies meet the standards more effectively?</i> ❖ <i>What is the impact on pharmacies after inspection, particularly for those without action plans? Does it provide a continuing focus for improvement?</i> ❖ <i>Are there any unintended positive/negative consequences of regulatory inspections?</i> ❖ <i>Is action planning an effective intervention leading to sustained improvement?</i> ❖ <i>Does action-planning lead to greater accountability/ involvement from</i>

		<p>pharmacy owners and superintendent pharmacists?</p> <ul style="list-style-type: none"> ❖ Are there any unintended positive/negative consequences associated with action plans? <p>Depth interviews with community pharmacy professionals:</p> <ul style="list-style-type: none"> ❖ Do you think the new approach is helping pharmacists bring about a cultural shift in community pharmacy practice? ❖ Do you think the new approach has the potential to drive better patient outcomes in the community pharmacy sector? ❖ Do you think the new approach can help end the current 'tick-box' approach to regulating community pharmacies? ❖ Do you think the new approach provides or will provide enough freedom to pharmacists to decide how best to meet the standards while ensuring better outcomes for patients? ❖ Do you think the new approach can help pharmacists sustain improvement and quality/safety of their services to patients? ❖ How far would you say that inspections provide a continuing focus for improvement? ❖ Do you think there are any other benefits to your business from undergoing inspections? ❖ Would you say that action planning is an effective tool to sustain improvement? ❖ Do you think that reporting and/or ratings provide an incentive for continued improvement in the community pharmacy sector? ❖ What impact or added value do you think publishing reports and ratings could entail for community pharmacies and patients in Great Britain? Are there any particular concerns you have about this proposal?
Priority areas for action / suggested improvements		
I. Assess whether there are any barriers that are undermining the success of the new approach	a) What is the opinion of stakeholders concerning the GPhC's intention to publish inspection reports and ratings? How can the policy be taken forward?	<p>Online census</p> <ul style="list-style-type: none"> ❖ If any standards are unclear, please detail the reasons why they are unclear and suggestions for how their clarity could be improved? ❖ Please provide any suggestions for how the process of developing an action plan, or the focus of action plans, could be improved. For example, are the timescales for agreeing action plans realistic? ❖ Are there possible improvements to inspection reporting to support their usefulness in improving future standards of patient care?

		<ul style="list-style-type: none"> ❖ <i>What more could be done to improve the value of inspections and drive higher standards in patient care?</i> <p>Depth interviews with inspectors and stakeholder organisations:</p> <ul style="list-style-type: none"> ❖ <i>Do the current GPhC standards set out clearly what a pharmacy needs to do to deliver effective patient care? If not, what could be made clearer?</i> ❖ <i>Feedback concerning the proposal to publish inspection reports and ratings</i> ❖ <i>Areas for potential improvement.</i> ❖ <i>Depth interviews with pharmacists: What more could be done to improve the value of inspections and drive higher standards in patient care?</i> ❖ <i>What could the GPhC do to improve the process of developing an action plan, or the focus of action plans?</i> ❖ <i>What could the GPhC do to improve the usefulness of reporting in improving future standards of patient care?</i>
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Annex 3 Survey questionnaire and interview guides

A3.1 Questionnaire – online census

Evaluation of the GPhC's approach to regulating community pharmacies

The GPhC wants your feedback about their current approach to regulating community pharmacies in Great Britain. We would appreciate a few minutes of your time to complete the short survey below.

This is an excellent opportunity for you to voice your opinion and any concerns about the current approach to regulating community pharmacies. Your views matter and will be taken on board by the GPhC to ensure continued improvements in the quality of pharmacy regulation the health and well-being of patients.

Introduction

The General Pharmaceutical Council (GPhC) has contracted **ICF Consulting Services Ltd (ICF)** to conduct an external evaluation of its approach to regulating community pharmacies.

In this study, we are surveying pharmacies regulated by the GPhC, including those not yet inspected under the new approach. The purpose is to better understand the impacts of the GPhC's activities on community pharmacies, pharmacy professionals and patients.

Additional information on the study

The purpose of the evaluation is to inform the GPhC whether it is achieving its objectives through its new approach to regulation and to learn from progress to date whether further changes are needed..

The new approach to regulating community pharmacies includes:

- Setting a clear set of standards, focused on outcomes for patients, which all pharmacies must meet;
- Conducting inspections of pharmacies to assess whether and how they are meeting the standards;
- Requiring action plans for those pharmacies deemed to require improvement; and
- Providing reports (including a rating or label) to pharmacies and publishing those reports.

How you can help

We greatly appreciate your participation in the survey below. The survey is mainly multiple-choice and should take no longer than **20 minutes to complete**.

The survey can be accessed at work or home via the link and unique code provided. This feature allows you to return to the survey if you are unable to complete it in a single sitting. Your response is automatically saved so there is no need to enter information twice.

We kindly request that you submit your survey response by no later than Friday 12 June 2015.

Your participation matters

Since the validity of the results depends on a high response rate, your participation is crucial to the success of this study. Results of this survey will feed back to the GPhC and contribute to improving the GPhC's regulatory approach.

Additional notes to the survey

- The survey can be submitted electronically. Alternatively, we are happy to send a version of the questionnaire in Word, which you can print and send to the following postal address: **ICF Consulting Services Ltd, Watling House, 33 Cannon Street, London EC4M 5SB.**
- As stated above, the deadline for submission is **Friday 12 June 2015**.
- If you have any queries about the survey or the study, please contact the **ICF survey team** at: **GPhC_Community_Pharmacies_Survey_2015@icfi.com**.
- If you would like to discuss the research with someone at the GPhC, please contact **Andy Jaeger** at andy.jaeger@pharmacyregulation.org.

We appreciate your input and thank you for contributing to this important study.

Part 1: Background information

Q1. Name of organisation:

Q2. Please provide your contact details:

Your name: _____

Job Title: _____

Address: _____

Email : _____

Contact telephone number: _____

Q3. What is your country of residence? (please choose as many options as apply):

- ☐ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland
- ☐ Other (please give details) : _____

Q4. In what capacity are you responding?

- ☐ As an individual
- ☐ On behalf of an organisation
- ☐ Other (Please specify): _____

Section 1A: Responding as an individual

Q5. Are you responding as?

- ☐ A pharmacy professional
- ☐ A member of the public
- ☐ Other (Please give details): _____

Section 1A (a): Pharmacy professionals

Q6. Are you:

- ☐ A pharmacist
- ☐ A pharmacy technician
- ☐ Other (please give details) _____

Q7. Please select the option below that best describes the primary area of your work:

- ☐ Community pharmacy
- ☐ Hospital pharmacy
- ☐ Primary care organisation / provider
- ☐ Pharmacy education, training and research

Section 1A (b): Community pharmacy

Q8. Please indicate what type of community pharmacy you work in:

- ☐ Multiple (community pharmacy with 6 or more branches)
- ☐ Independent (community pharmacy with 1-5 branches)

Q9. Which of the options below best describes your role in the pharmacy? (please choose as many options as apply)

- ☐ Superintendent
- ☐ Business owner (pharmacist)
- ☐ Business owner (non-pharmacist)
- ☐ Responsible pharmacist
- ☐ Locum
- ☐ Employee
- ☐ Other (please give details): _____

Section 1B: Responding on behalf of an organisation

Q10. Please choose an option below that best describes your organisation

- ☐ Community pharmacy
- ☐ Hospital pharmacy
- ☐ Primary care organisation/provider
- ☐ Pharmacy education, training and research
- ☐ Pharmaceutical industry
- ☐ Body/ organisation representing patients/the public
- ☐ Body/ organisation representing professionals/practitioners
- ☐ Body/organisation representing trade industry
- ☐ Government department/organisation
- ☐ Regulatory body
- ☐ Other (please give details): _____

Section 1B: Responding on behalf of an organisation

Q11. Please indicate what type of community pharmacy you work in:

- ☐ Multiple (community pharmacy with 6 or more branches)
- ☐ Independent (community pharmacy with 1-5 branches)

Q12. Which of the options below best describes your role in the pharmacy? (please choose as many options as apply):

- ☐ Superintendent
- ☐ Business owner (pharmacist)
- ☐ Business owner (non-pharmacist)
- ☐ Responsible pharmacist
- ☐ Locum
- ☐ Employee
- ☐ Other (please give details): _____

Part 2: Standard-setting

Q13. How would you describe your level of awareness of the GPhC's *Standards for registered pharmacies* (Please ✓ which statement best reflects your level of awareness)?

	1. I am aware of all standards	2. I am aware of most, but not all standards	3. I am aware of some standards	4. I have limited awareness of standards	5. This is the first time I have been made aware of the standards

Q14. The *Standards for registered pharmacies* are grouped under five principles. Please indicate for each your level of understanding and implementation of the standards.

Standard	Please ✓ which statement best reflects your view					
	1. Clearly understood and fully implemented	2. Clearly understood and partially implemented	3. Clearly understood and not implemented	4. Unclear and fully implemented	5. Unclear and partially implemented	6. Unclear and not implemented
The governance arrangements safeguard the health, safety and well-being of patients and the public						
Staff are empowered and competent to safeguard the health, safety and well-being of patients and the public						
The environment and condition of the premises from which pharmacy services are provided, and any associated premises, safeguard the health, safety and well-being of patients and the public						
The way in which pharmacy services, including the management of medicines and medical devices, are delivered safeguards the health, safety and						

well-being of patients and the public						
The equipment and facilities used in the provision of pharmacy services safeguard the health, safety and well-being of patients and the public						

Q15. The GPhC has identified key outcomes that patients and the public should experience using pharmacy services. Please indicate for each how far you have understood and implemented the relevant standards.

Outcome	Please ✓ which statement best reflects your view					
	1. Clearly understood and fully implemented	2. Clearly understood and partially implemented	3. Clearly understood and not implemented	4. Unclear and fully implemented	5. Unclear and partially implemented	6. Unclear and not implemented
Pharmacy staff are knowledgeable and experienced						
Patients are given the information or advice they need by the pharmacy staff						
Patients' privacy is maintained during their discussions with pharmacy staff						
Patients are given enough time to speak with someone at the pharmacy						
Patients are asked questions by the pharmacy staff to make sure they are given the best advice						
Patients are treated with respect by the pharmacy staff						
The pharmacy is clean and properly maintained						
Patients are able to access the						

pharmacy services they need						
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Q15a. If any standards are unclear, please give the reasons and suggestions for how their clarity could be improved.

Q16. Do you think that the standards encourage you to increase your focus on patients and users of your services?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q16a. How important are standards in helping you focus on patients and users of your services. Please indicate how far you agree with the following statements.

Outcome	1. Strongly agree	2. Agree	3. Neither agree nor disagree	4. Disagree	5. Strongly disagree	6. Don't know
<i>As a result of the standards ...</i>						
... we regularly review and monitor the safety and quality of our pharmacy services						
... we maintain all necessary records for the safe provision of pharmacy services at our premises						
... we actively seek to protect the privacy, dignity and confidentiality of patients and the public who receive our pharmacy services						
... we ensure our staff have the appropriate skills, qualifications and competence for the safe and effective provision of the						

Outcome	1. Strongly agree	2. Agree	3. Neither agree nor disagree	4. Disagree	5. Strongly disagree	6. Don't know
<i>As a result of the standards ...</i>						
pharmacy services we provide						
... we raise concerns when medicines or medical devices are not fit for purpose						
,,, we ensure that all medicines and medical devices we provide are: obtained from a reputable source; are safe and fit for purpose; and are stored and/or disposed of securely						
,,, we ensure that our equipment and facilities are obtained from a reputable source; are safe and fit for purpose; and are stored and/or disposed of securely						
Other (please specify):						

Q17. Are there instances where your pharmacy practices go beyond the level required by the standards?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q17a. Please provide details

Part 3: Inspections

Q18. Has your pharmacy been inspected by the GPhC since 4 November 2013?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q19. How important is inspection for encouraging you to focus on patients and users of your service?

1. Very important	2. Somewhat important	3. Neither important nor unimportant	4. Somewhat unimportant	5. Very unimportant

Q20. Thinking about inspections, please indicate what information and guidance you find helpful?

	Please ✓ how helpful you find the following				
	1. Very helpful	2. Somewhat helpful	3. Neither helpful nor unhelpful	4. Somewhat unhelpful	5. Very unhelpful
Advance notification from the GPhC					
The GPhC's <i>Standards for registered pharmacies</i>					
Information available on the GPhC's website					
The GPhC's inspection decision-making framework					
Information provided by other organisations (such as the Royal Pharmaceutical Society or the National Pharmacy Association)					
Other (Please specify)					

Q21. Please indicate the elements of inspection most important for meeting and further improving standards.

	1. Very important	2. Somewhat important	3. Neither important nor unimportant	4. Somewhat unimportant	5. Very unimportant
Involving the whole pharmacy team					
Being able to demonstrate how standards are being met					

The inspector signposting good practice					
Evidence being gathered					
A report which records the evidence					
Feedback from the inspector					

Q22. Has your level of awareness of the GPhC's standards improved as a result of your inspection?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q23. Please describe how much time you spent in relation to inspection.

1. A few hours	2. About a day	3. A few days	4. About a week	5. Up to a month	6. More than a month	7. Don't know

Q24. What more could be done to improve the value of inspections and drive higher standards in patient care?

Part 4: Action-planning

Q25. Has your pharmacy been required to develop an action plan by the GPhC, as a result of your inspection?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q25a. What were the main areas you highlighted in your action plan? (Please choose as many options as apply)

- ☐ Governance arrangements
- ☐ Staff competence

- ☐ Environment and condition of the premises
- ☐ Delivery of pharmacy services
- ☐ Equipment and facilities
- ☐ Other (please give details): _____

Q26. Please indicate how helpful you find elements of action planning to improve standards of patient care at your pharmacy?

Element of action planning	Please ✓ how helpful you find the following				
	1. Very helpful	2. Somewhat helpful	3. Neither helpful nor unhelpful	4. Somewhat unhelpful	5. Very unhelpful
Reflecting on the inspector's findings					
Assessing how well you are meeting standards					
Defining priorities for improvement					
Assigning responsibilities					
Providing follow up evidence to the GPhC					
Being re-inspected					

Q27. Please provide any suggestions to improve the process of developing an action plan, or the focus of action plans. For example, are the timescales for agreeing action plans realistic?

Part 5: Reporting and publication

Q28. Thinking about the provision of inspection reports and ratings, please rate how far you agree with the following statements

	Please ✓ how useful you find the following				
	1. Strongly agree	2. Agree	3. Neither agree nor disagree	4. Disagree	5. Strongly disagree
Pharmacies perceive the inspection report to be accurate					
Reports are valuable to think about and implement improvements in quality and performance					
Reports help focus efforts on the areas of most relevance to patient safety					

Inspection reports are sufficient to support the inspection judgment and rating					
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Q29. Could improvements be made to inspection reporting to support their effectiveness in improving future standards of patient care?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q29a. If yes, please provide suggestions.

Q30. The GPhC is planning to publish inspection reports and ratings (subject to the necessary legal powers). Do you think this will have any added value for pharmacies and patients?

1. Yes	2. No	3. Prefer not to answer	4. Don't know

Q30a. How do you think publishing inspection reports and ratings could impact on pharmacies and patients? Please state the degree to which you agree with the following statements.

Outcome	1. Strongly agree	2. Agree	3. Neither agree nor disagree	4. Disagree	5. Strongly disagree	Don't know
<i>The act of publishing reports/ratings could...</i>						
... help improve sector performance (i.e. encourage pharmacies to provide safe and effective services to patients and users of their services and sustain such practices)						
... provide greater scope for community pharmacies to learn from one another by sharing knowledge and good practice in pharmacy care						
... increase accountability of pharmacy owners						

Outcome	1. Strongly agree	2. Agree	3. Neither agree nor disagree	4. Disagree	5. Strongly disagree	Don't know
<i>The act of publishing reports/ratings could...</i>						
(i.e. to ensure they adequately train staff for the safe delivery of pharmacy services to patients and users)						
... increase patients' trust in pharmacy care and in pharmacists' clinical expertise						
... increase patients' choice by providing information about the performance of different pharmacies						
.... provide greater opportunities for pharmacies to take on new responsibilities, for example in primary care services						
Other (please specify)						

Thank you for taking time to complete this questionnaire.

A3.2 Interview topic guide – stakeholders

1. Introduction

My name is XXXX and I'm calling from ICF. We have an interview scheduled today to hear your views on certain aspects of the GPhC's current approach to regulating community pharmacies in Great Britain.

The interview is part of an evaluation study the GPhC has commissioned ICF to undertake. The main objectives of the study are: (1) to assess whether the new approach to regulation is consistent with the GPhC's objectives; (2) to test whether the new interventions (introduced as part of the new regulatory approach) are effective; and (3) identify priority areas for action, that is, changes the GPhC should consider to develop and/or improve the current approach.

We would appreciate you drawing as much as possible on your experience of inspections throughout the interview.

1. Setting and monitoring standards

- do the current GPhC standards set out clearly what a pharmacy needs to do to deliver effective patient care? If not, what could be made clearer?
- Based on your inspections so far, what can you say about the level of awareness of GPhC standards among pharmacists and pharmacy professionals? How could this be enhanced?
- Do pharmacies use the GPhC's standards and other information available on the website? If so, how and why?
- Do pharmacies consult information provided of relevance to the standards, for example, by the Royal Pharmaceutical Society or National Pharmacy Association? If so, how and why?
- Do pharmacies actively engage in meeting the standards, or are they seen as a reference tool for inspections?
- Do the standards encourage pharmacies to focus on patients and users of their services? If so, how?
- Have the standards helped change a culture previously focused on rules and compliance, towards outcomes, professional decision making and improvement?
- Are there any unintended consequences of introducing the new outcome focused standards for pharmacy premises?

2. Inspection

- How far does the [GPhC's] approach focus on outcomes, drive improvement and is applied consistently by the inspectors?
- How do pharmacies experience inspections (e.g. how do pharmacies prepare for inspection; is advance notification helpful)?
- How helpful is the GPhC's inspection decision-making framework when thinking about inspections?
- Does the level of awareness of standards change as a result of inspection?
- Do inspections help pharmacies meet the standards more effectively?
- Which elements of an inspection – involvement of the whole pharmacy team, facilitating learning and good practice, collecting and agreeing evidence – are most important in supporting pharmacies to meet the standards and to improve?

- What is the impact on pharmacies after inspection, particularly for those without action plans? Does it provide a continuing focus for improvement?
- Are there any unintended positive/negative consequences of regulatory inspections?

3. Action planning

- Is action planning an effective intervention leading to sustained improvement?
- Where an action plan is needed, are the right areas highlighted in inspection reports to improve quality, including safety?
- Does action-planning lead to greater accountability/involvement from pharmacy owners and superintendent pharmacists?
- Are there any unintended positive/negative consequences associated with action plans?

4. Reporting and publication

- Does the provision of inspection reports and ratings provide an incentive for continued focus on quality provision of pharmacy services and improvement?
- Feedback concerning the proposal to publish inspection reports and ratings

5. Other

- Any other points the interviewee would like to raise, including potential areas for improvement.

Thank you and close.

A3.3 Interview topic guide – pharmacists

1. Introduction

My name is XXXX and I'm calling from ICF. I am calling about your recent participation in our survey, co-launched with the GPhC. You may recall, ICF has been commissioned by the GPhC to conduct an evaluation of their current approach to regulating registered community pharmacies in Great Britain.

Your survey response was very insightful and we would like to hear more about your experiences and opinions in a short telephone interview. Can you spare a few minutes? If not, could you suggest a more convenient date and time?

2. General information

1. Name of interviewee:
2. Can you confirm your position in the business?
3. Can you confirm that you work for an independent or a multi-chain pharmacy? [INSERT ANSWER FROM SURVEY – Q35/]

3. General views on inspections – ASK THOSE WHO HAVE BEEN INSPECTED UNDER THE NEW APPROACH

1. Confirm with the interviewee that they have been inspected under the new approach
[INSERT ANSWER FROM SURVEY – Q20/]
2. How did you prepare for your most recent inspection?
Probe: what was the whole process of inspection like – from being notified, preparing for the inspection and engaging with inspectors on the day of the inspection? Were there any differences in the inspection process between the old approach and the new approach? Which ones?
3. Were there any costs involved in preparing for inspections (excluding having to meet an action plan if relevant)? Would you be able to quantify? Were these significantly different from what you have incurred from past inspections?
4. You mentioned you spent about [INSERT ANSWER FROM SURVEY – Q25] of your staff's time dealing with your most recent inspection. Is that correct? Would you say that is roughly the same time you've always spent on inspections? Would you say the new approach constitutes a greater or a lesser time burden than the previous approach? Why?
5. If you were to assess GPhC inspections against other inspections you've experienced so far from other regulatory bodies, would you say that GPhC inspections place a higher or lower burden on time and financial resources? Or are they all about the same?

There are specific aspects of inspections you cited as **important** or **very important** in helping you meet the GPhC standards and improve. These include [INSERT ONE OR TWO OF THE ABOVE ASPECTS FROM QUESTION 23]:

1. ...
2. ...

Involving the whole pharmacy team
Being able to demonstrate how standards are being met
The inspector signposting good practice
Gathering evidence
A report recording the evidence
Feedback from the inspector

Could you explain how these aspects of the inspection matter to you, your staff and the pharmacy in general?

Probe: Do you have any examples of how these elements have helped the pharmacy in improving and driving better outcomes?

6. How far would you say that inspections provide a continuing focus for improvement? Can you provide some examples?

Probe: Is there any specific advice you received during the inspection which led you to make changes to: (1) internal processes/procedures (e.g. Standard Operating Procedures (SOPs)); (2) services you provide to patients and customers. Do you regularly monitor how changes are being implemented in the pharmacy? How? (e.g. do you incentivise staff to implement changes and to remain compliant, etc.)?

7. Are there **any other benefits** to your business from undergoing inspections?

Probe: additionally, would you say there are any unintended consequences to your business from undergoing inspections?

8. You've said in your survey response that, to improve the value of inspections and drive higher standards in patient care ... [PROVIDE A SUMMARY - INSERT ANSWER FROM SURVEY – Q26]

Can you explain your response in more detail? Anything else you'd like to add?

Note to the interviewer! Respondent may not have provided an answer in the survey – simply ask what could the GPhC do to improve....

4. General views on inspections – ASK THOSE WHO HAVE NOT BEEN INSPECTED UNDER THE NEW APPROACH

9. How do you normally prepare for inspections carried out by the GPhC?

Probe: what was the whole process of inspection like – from being notified, preparing for the inspection and engaging with inspectors on the day of the inspection?

10. Approximately, how much does your business spend as a result of inspections (excluding having to meet an action plan if required)? Can you estimate roughly how much of your staff's time was spent dealing with your most recent inspection?

11. If you were to assess GPhC inspections against other inspections you've experienced from other regulatory bodies, would you say that GPhC inspections place a higher or lower burden on time and financial resources? Or are they all about the same?

12. As part of their new regulatory approach, the GPhC has introduced a new inspection model focusing on certain key elements, including:

Involving the whole pharmacy team
Enabling pharmacies to demonstrate how standards are met
Signposting good practice
Gathering evidence
Recording and reporting gathered evidence
Providing feedback for improvement

Which of the above are the most important in helping you achieve compliance and improve the quality and safety of your services? (choose up to 3). Why?

13. How far would you say inspections provide a continued focus for improvement? Can you provide examples?

Probe: Is there any specific advice you received during the inspection which led you to make changes to: (1) internal processes/procedures (e.g. Standard Operating Procedures (SOPs)); (2) services you provide to patients and customers. Do you regularly monitor how changes are being implemented in the pharmacy? How? (e.g. do you incentivise staff to implement changes and to remain compliant, etc.)?

14. Are there **any other benefits** to your business from undergoing inspections?

Probe: additionally, would you say there are any unintended consequences to your business from undergoing inspections?

15. What more could be done to improve the value of inspections and drive higher standards in patient care?

5. Action-planning – ASK ALL (I.E. INSPECTED AND NOT YET INSPECTED)

- 16.a) *If inspected under the new approach*

You mentioned in your survey response that **you were required** [INSERT ANSWER FROM SURVEY – Q27] to develop an action plan following your most recent inspection

- b) If not inspected under the new approach*

Have you had to develop an action plan following your most recent inspection?

17. Would you say that action planning is an effective tool to sustain improvement? Could you explain?

18. In your survey response, you explained that there are certain elements of action planning that are important or very important in helping you improve standards of patient care at your pharmacy. These include: [INSERT ANSWER FROM SURVEY]

Element of action planning
Reflecting on the inspector's findings
Assessing how well you meet standards
Defining priorities for improvement
Assigning responsibilities
Providing follow up evidence to the GPhC
re-inspection

Could you explain why?

19. You said in your survey response that, to improve the process of developing an action plan, or the focus of action plans, PROVIDE A SUMMARY - INSERT FROM SURVEY: Q29] Could you explain your response in more detail? Is there anything else you'd like to add?

Note to the interviewer! Respondent may not have provided an answer in the survey – simply ask what do you think the GPhC could do to improve

6. Reporting and publication

20. Do you think that reporting and/or ratings provide an incentive for continued improvement in the community pharmacy sector?
21. In the survey, we asked whether the publication of inspection reports and ratings could add significant value to the community pharmacy sector. In your response, you said that:

[INSERT FROM SURVEY]

Outcome
[1] ... help improve sector performance (i.e. encourage pharmacies to provide safe and effective services to patients and users of their services and sustain such practices)
[2] ... provide greater scope for community pharmacies to learn from each other by sharing knowledge and good practice in pharmacy care
[3] ... increase accountability of pharmacy owners (i.e. to ensure they adequately train staff for the safe delivery of pharmacy services to patients and users)
[4] ... increase patients' trust in pharmacy care and in pharmacists' clinical expertise
[5] ... increase patients' choice by providing information about the performance of different pharmacies
[6].... provide greater opportunities for pharmacies to take on new responsibilities, for example in primary care services

Could you explain your answer(s)?

22. What impact or added value do you think publishing reports and ratings could entail for community pharmacies and patients in Great Britain?
23. Are there any particular concerns you have about this proposal?
24. You've said in your survey response that certain improvements could be made to inspection reporting to support their effectiveness in improving future standards of patient care, including [PROVIDE SUMMARY – INSERT ANSWER FROM SURVEY – Q32]

Could you explain your response in more detail? Is there anything else you'd like to add?

Note to the interviewer! Respondent may not have provided an answer in the survey – simply ask what do you think the GPhC could do to improve

Perceived impacts

25. Through this new approach, the GPhC is hoping to:

(1) generate a culture shift in community pharmacy practice – one that ensures community pharmacists meet the required standards but increasingly focus on outcomes and improvement and strive to put their patients and users of their services first.

(a) Do you think the new approach is helping pharmacists achieve that?

Probe: Has the new approach, in any way (for example through inspections), prompted you to improve patient outcomes at your pharmacy? Could you provide some examples (i.e. are there any new or innovative services that you provide to your patients)?

(b) Do you think the new approach has the potential to drive better patient outcomes in the community pharmacy sector? If so, how do you see the sector in five years' time?

Probe: do you think we will start to see a shift from traditional dispensing to more clinical care (e.g. diagnosis/treatment services) in the community pharmacy sector?

(2) the GPhC hopes that more pharmacies will actively engage in achieving and sustaining compliance and improvement.

(a) Do you think the new approach can help end the current “tick-box” approach to regulating community pharmacies? Why?

(b) Does the new approach provide enough freedom to pharmacists to decide how best to meet the standards while ensuring better outcomes for patients? If not, can this be achieved in the near future?

(c) Do you think the new approach can help pharmacists sustain improvement and quality/safety of their services to patients? Why?

Annex 4 Survey routings

Question number	Type of question	Routing
Part 1: Background information		
1	Not mandatory, personal information requested (name of organisation)	None
2	Mandatory, personal information requested (contact details of participant)	None
3	Not mandatory, multiple answers possible	None
4	Not mandatory, only one answer possible	<p>If “responding as an individual” → Section 1A : responding as an individual;</p> <p>If “responding on behalf of an organisation” → Section 1B : responding on behalf of an organisation;</p> <p>If “other” → Part 2 : standard-setting</p>
Section 1A: Responding as an individual		
5	Not mandatory, only one answer possible	<p>If “responding as a pharmacy professional” → Section 1A (a) : pharmacy professionals;</p> <p>If “responding as a member of the public” → Part 2 : standard-setting;</p> <p>If “other” → Part 2 : standard-setting</p>
Section 1A (a): Pharmacy professionals		
6	Not mandatory, only one answer possible	None
7	Not mandatory, only one answer possible	<p>If “community pharmacy” → Section 1A (b) : community pharmacy;</p> <p>If “hospital pharmacy” → Part 2 : standard-setting;</p> <p>If “primary care organisation / provider” → Part 2 : standard-setting;</p> <p>If “pharmacy education, training and research” → Part 2 : standard-setting</p>
Section 1A (b): Community pharmacy		
8	Not mandatory, only one answer possible	None
9	Not mandatory, multiple answers possible	None
Section 1B: Responding on behalf of an organisation		
10	Not mandatory, only one answer possible	If “community pharmacy” → Section 1B (a) : community pharmacy;

Question number	Type of question	Routing
		<p>If “hospital pharmacy” → Part 2 : standard-setting;</p> <p>If “primary care organisation / provider” → Part 2 : standard-setting;</p> <p>If “pharmacy education, training and research” → Part 2 : standard-setting;</p> <p>If “pharmaceutical industry” → Part 2 : standard-setting;</p> <p>If “body/organisation representing patients/the public” → Part 2 : standard-setting;</p> <p>If “body/organisation representing professionals/practitioners” → Part 2 : standard-setting;</p> <p>If “body/organisation representing trade/industry” → Part 2 : standard-setting;</p> <p>If “government department/organisation” → Part 2 : standard-setting;</p> <p>If “regulatory body” → Part 2 : standard-setting;</p> <p>If “other” → Part 2 : standard-setting</p>
Section 1B (a): Community pharmacy		
11	Not mandatory, only one answer possible	None
12	Not mandatory, multiple answers possible	None
Part 2: Standard-setting		
13	Not mandatory, only one answer allowed	None
14	Not mandatory, only one answer allowed per row	None
15	Not mandatory, only one answer allowed per row	None
15a	Not mandatory, open-ended text response	None
16	Not mandatory, only one answer allowed	If “yes” or “no” → Q16a
16a	Not mandatory, open-ended text response	None
17	Not mandatory, only one answer allowed	If “yes” → Q17a
17a	Not mandatory, open-ended text response	None
Part 3: Inspections		

Question number	Type of question	Routing
18	Not mandatory, only one answer allowed	If “yes” → Q19; Q20; Q21; Q22; Q23; Q24; and Q25 If “no” → Part 4 : action-planning
19	Not mandatory, only one answer allowed	None
20	Not mandatory, only one answer allowed per row	None
21	Not mandatory, only one answer allowed per row	None
22	Not mandatory, only one answer allowed	None
23	Not mandatory, open-ended text response	None
24	Not mandatory, only one answer allowed	None
25	Not mandatory, open-ended text response	None
Part 4: Action-planning		
26	Not mandatory, only one answer allowed	If “yes” → Q26a; Q27; and Q28 If “no”; “prefer not to answer”; “don’t know” → Part 5 : reporting and publication of ratings
26a	Not mandatory, open-ended text response	None
27	Not mandatory, only one answer allowed per row	None
28	Not mandatory, open-ended text response	None
Part 5: Reporting and publication of ratings		
29	Not mandatory, only one answer allowed per row	None
30	Not mandatory, only one answer allowed	If “yes” → Q30a
30a	Not mandatory, open-ended text response	None
31	Not mandatory, only one answer allowed	If “yes” or “no” → Q31a
31a	Not mandatory, open-ended text response	None

Annex 5 Notes of depth interviews with stakeholder organisations

1. Setting and monitoring standards

In your view, do the current GPhC standards set out clearly what a pharmacy needs to do to deliver effective patient care? If not, what could be made clearer?

Stakeholder organisation 1 (SO1): Yes, but the standards are largely subjective. This is because it is a principles based approach. The standards have a very broad definition, and show what pharmacies need to consider, but they do not include much guidance which identifies specific courses of action. The previous standards were more “tick box”, telling pharmacists exactly what they needed to do.

There used to be many documents detailing the standards, so people always had access to them. However, because the standards were so specific, if a standard didn't exist for a particular topic or theme then pharmacists were “left scratching their heads” as they were used to being provided with the answer.

I believe that the standards do cover the correct issues to deliver effective patient care (“you can't argue that the standards do not apply to delivering effective patient care”) I feel that it would be helpful to have some documents providing illustrative examples of how to comply with the standards – some examples of best practice.

SO2: Yes, the standards are set out clearly and are well designed. There is lack of discrimination between pharmacies.

SO3: Yes, they do – they are really clear.

SO4: The standards are clear and the vast majority of pharmacists who read the standards know what it means. Some of the standards are a bit trickier to follow but most standards are more or less straightforward and clear for the people to understand them.

SO5: The standards state what the requirements are quite clearly. However, they do not provide any guidance about how to achieve the standards, or what constitutes good. I am fine about what is covered in the standards though.

I realise why the standards do not offer any guidance – I feel that it is not the role of the regulator and some regulators are not comfortable with providing guidance. However, pharmacists are used to getting help and guidance around standards, and under the old system they received guidance.

I feel the guidance could come in the form of “what other people have done and why this has been accepted” rather than just giving an example of what is good.

SO6: If you ask 20 pharmacies you will get 20 different opinions. We are pretty clear and very supportive of the direction of travel. The GPhC would not follow the previous regulator's approach of trying to nail down everything that happens in pharmacy in some sort of regulatory context. The GPhC concentrates on what the outputs would be or the outcome and would not prescribe how people may get there. That is an approach we continue to support. That is not to suggest it is a challenging approach for some of our colleagues and members. It is very different from the old approach. People want to know what they can and can't do and the old regulator would oblige by providing a code of ethics of 20 pages. They provided detailed dos and don'ts.

The idea is now to apply and illustrate some broad brush principles and standards, which we support but recognise the challenges, which make some people uncomfortable. Pharmacists like detail and like things to be black and white. They are interested in specifics – 8 not 9 pills, the right drugs not ones that are very similar. If you get that wrong it's a criminal offence. So a code that is

written in the way that the GPhC has written this, while the rationale is understood, it is quite a challenge for those who like to be told what is what.

We [...] have done what [we] can to help people to interpret and understand it. E.g. last year with the new inspection schedule, the [...] had a roadshow programme to help its members 'get through' an inspection visit.

I think there is always a good case for giving examples of what "good" looks like. That should of course evolve over time as owners and operators get more familiar with what is expected. We had an ongoing issue about the grading of the inspection and I don't think people are still clear what excellent looks like. No one understands what "innovation" means in that context. There are calls out in the market place for the whole system to be scrapped because people don't understand it and don't see a value in it. We were very supportive of the move away from past failures. The fail was far too big a bullet to hold to peoples head. There were too few inspections that resulted in action being taken beyond warning letters and stuff. The sanctions were never put in place.

There is a general acceptance that the interests of the public that some form of grading is ok. I would be wrong if I was pretending people were not reluctant about it and would just like to go back to a pass or fail, but with the new standards in place.

A feeling of what good looks like in practice would be helpful to our colleagues.

SO7: The GPhC's approach is entirely in line with modern regulation, the outcome based approach, greater transparency – looking to publish inspectors reports. Patients and public really want to see the work that we have been doing recently on consultation. The approach of avoiding regulatory burden is an important principle that I know that they have at the heart of decision making. The work we have done with them is about having clarity in accountability – so when is the owner accountable, when is the superintendent pharmacist or others accountable. GPhC's approach very much in line with other regulators and what ministers would want to see.

SO8: I think they do – the principles based approach is positive in a sense that it allows a certain degree of freedom for the pharmacy to demonstrate how they are delivering the standards. It has been quite a culture shift for pharmacists to get where they are now but perhaps more guidance could be better but fundamentally we are happy with the approach that was taken.

What can you say about the level of awareness of GPhC standards among pharmacists and pharmacy professionals? How could awareness be enhanced?

SO1: I feel the awareness of the standards is high among pharmacists. I feel there "is a concern for pharmacists that the inspector might call." It is like preparing for an exam. However, I feel that although the coverage of the new standards is good, there are some areas it does not cover. An example of this is the management of repeat prescription collection services. As the guidance doesn't cover this, pharmacists look back at the old RPS guidance, but this does not necessarily apply any more.

SO2: The level of awareness is high. Pharmacies are aware of the standards.

SO3: I can only give an anecdotal answer as I'm not based in a pharmacy. I'm working for a [...]. I think it's fair to say that when the standards first came out and the inspections that go with them first started to happen, people were quite worried. I did go along to a couple of training sessions hosted by various different organisations and listened to the comments people had about the visits they had experienced up to that point. I think generally people were quite unhappy, in particular about not being informed of when visits would actually take place. Often inspections were carried out when the owner or superintendent pharmacist was away and given the quick turnaround often required for action plans, management could not be involved.

But I get the feeling that some of these issues are less common now, although as I've said before, as I haven't been subject to inspections myself I can only go with anecdotal evidence. But the mood seems to be a happier one.

On whether awareness should be enhanced: there has been a rapid sharing of knowledge. I think what still needs to be promoted is the greater involvement of the counter staff and/or lower-paid staff as part of inspections. I think staff needs to know that it's no longer the pharmacist's responsibility to provide evidence during inspections, they have a role to play too. Staff therefore needs to be made clear about internal procedures (e.g. SOPs), take them on board, and be able to demonstrate how they comply on a day-to-day basis.

SO4: The [...] observed that all events on the GPhC inspection model are very well attended and are successful in making people familiarised with the new standards. There is a big interest to participate to those events and to understand what those standards are but also to find out more about top tips that they have to provide. People take the time to come in and listen to those sessions in order to become familiar with these standards.

SO5: There is rising awareness among pharmacists. This is down to the number of inspections being carried out under the new regulation. Pharmacists become more aware after an inspection. This is because the standards set a lot of requirements out, and these don't become second nature until there is an inspection. It is not down to pharmacists ignoring the regulations, but they are very similar to the previous ones so pharmacists probably don't take it all in until the inspection.

There isn't really any way it could be enhanced – the standards are readily available and were widely advertised.

SO6: Still gaps, there is an inevitability that some people will think that by and large I get on with the day job, do a good job, don't get complaints from the customers and that 'I will have to think about it at some point, and will think about it when I get to it'.

The attendance at the [...] roadshows and anything talking about the inspection process - always has a huge attendance. The fact that people flock to those meetings suggests that people want to know more. They also want to be assured that some of the concerns that have been expressed on their behalf such as organisations like ours, have been addressed.

We were at a point where 96-97 per cent of pharmacies were being graded as "satisfactory", which is below half way and people were saying, well that cannot possibly be right. Is there any other regulator anywhere a 4 point scale and end up with 96 per cent at one point, then unsurprisingly people were a little bit concerned about that and therefore also wanting to get information that the GPhC is responding appropriately. There are still quite a lot of people out there who want to know what excellent looks like.

You can always have better awareness, can't have good awareness when no one has had chance to experience it. The same is true of the person regulation side which is at the moment a CPD assessment exercise. Haven't been through that yet, we are nearly at the end of the first cycle.

There has been a lot of effort put in up front, larger companies have had area manager meetings and gatherings to pick apart early inspections, to work out how much they can learn from that and how much they can then learn from teams.

Pretty good but can always do more. I would add that the GPhC has been very busy in getting the messages across and have been open and out there helping people to learn along the way.

SO7: My only insight is attending one of GPhC's stakeholder engagement events. Where different pharmacy interests larger and smaller independent pharmacies were sharing their perspectives.

Whilst there are issues about categorisation etc, my general take home was that there is support for this approach compared to previous approaches. See this as a positive step forward, may not be perfect yet but people see it as better than what there was before.

SO8: Pharmacies are certainly aware that there is a new inspection regime in place. Pharmacies are also aware that the new approach is more about demonstrating activities they are doing to fulfil the principles but they do not seem to understand what is involved in demonstrating that they are. For example, people struggle how much preparation they would need to do ahead of an inspection.

Do pharmacies use the GPhC's standards and other information available on the website? If so, how and why?

SO1: I believe that most pharmacists probably find out about the standards through GPhC, but do not know for sure. Some people do access the standards through other organisations, such as the RPS. However, these are fee paying organisations, so not everyone has access to them. In any case, they only tell them what the standards are, there is no additional information.

SO3: Yes, I think they do. There are various courses I've attended which were run by the NPA. The turnout was significant (for some of the courses I went to although one was on a Saturday morning and the other on a Sunday morning). People clearly at that point saw the significance of attending training courses. I think generally they are using these resources.

SO4: [...] used the GPhC website during their training, but the majority of people prefer to use the training materials that has been developed by organisations such as the NPA. Because it's laid out in a format that assist them in a better way and provide them with some examples. The NPA has done video with the GPhC team, and consistently refers about the GPhC website to read the standards.

SO5: I do not know where the pharmacists get their information from. I suspect most of them get it from the GPhC website as this seems logical, but I have never asked pharmacists about sources of information.

I suspect a lot of information about the standards and what happens at inspections is disseminated at professional events. The pharmacists will discuss the standards and the approaches taken during inspections.

SO8: There are a couple of places – independents tend to use NPA. For multiples [...] have pulled together guidance documents and FAQs, i.e. creating information within the company and support sharing of that knowledge.

Do pharmacies consult available information relevant to the standards, for example, by the Royal Pharmaceutical Society or National Pharmacy Association? If so, how and why?

SO1: As mentioned above, I believe some people access information through RPS on standards. But more likely is that pharmacists are accessing information from the professional bodies for information where the standards don't exist (Repeat Prescription collection service) or to access guidance on what good looks like to fit in with the standards.

SO2: Yes, they do. Mostly the information available on the websites of NPA and RPS. Also GPhC. The RPS website offers guidance documents, and they have support teams in place which pharmacies can call for help and advice.

SO5: I do not know.

Do pharmacies actively engage in meeting the standards, or are they merely seen as a reference tool for inspections?

SO1: Yes, I believe pharmacists like to know that they are meeting the standards set. However, I do not know whether this is because they are being inspected and they want to get a good rating or if they would do it in the absence of an inspection. However, this was always the case under the previous inspection system as well.

SO2: Yes, they do. However, there is more guidance needed with regards to what “satisfactory” means. Most people have issue with was the grading satisfactory. The satisfactory makes people very demotivated, because if you have not got an action plan to fill in when you get a satisfactory then you should be under a good grade. So for a vast majority of pharmacies to come under satisfactory does not portray a good image of the profession. At the same time, it is not clear what poor means.

SO3: I think when the standards just came out, everybody thought it would just be a slightly different tick-box exercise they are used to. But I’ve heard individual pharmacists telling me how they felt that they’ve been put “through the ringer” by the end of the 2-4 hour visit. They never expected it to be that intense. I am confident that pharmacists and contractors, in particular, will now be going away and doing a lot of CPDs on the back of these inspections.

SO4: The vast majority of pharmacists have in mind that they have to provide the best care for patients and most of them are delivering a great service to make sure patients are top of the agenda. But there is also an element when the inspectors call, or when they are due for inspections, that they go for extra efforts to make sure that things are done the right way and that the staff is involved.

SO5: Yes, I believe pharmacists like to know that they are meeting the standards that are set. However, I do not know whether this is because they are being inspected and they want to get a good rating or if they would do it in the absence of an inspection. However, this was always the case under the previous inspection system as well.

SO6: More likely to rely in people to help them to do that. Not sure they would see new standards and wonder how to apply them. It would be nice to think that would be how it works, but not sure it is. If you’re an employee you will look to your employer and the larger employers should have a great deal of investment in informing and updating people on what is going on. Employers have reviewed and refreshed thinking about appraisal systems and we have helped some of them to do that because systems may be part of the evidence someone may rely on in future for ‘fitness to practise’. Also look to their trade associations to support them. A lot of this naturally would come from the superintendent’s departments or the superintendent pharmacists themselves.

SO8: Pharmacies are not using the new approach as part of their everyday life, they rather do that only when inspections are due, i.e. they look at their process and assess how they fit with GPhC standards. In other words, what pharmacies do every day is in itself evidence of the standard, but they do not think about fulfilling their standards during their daily activities. I.e. they do not think “I am doing this to meet GPhC’s standards...”.

Do the standards encourage pharmacies to focus on patients and users of their services? If so, how?

SO1: I believe that pharmacies look to meet the standards first and foremost. Once they feel that they have met the standards, a proportion of pharmacists will look to improve patient experience. The standards allow this to happen as they are not prescriptive.

SO2: They will do but we are likely to see that in the second round of inspections. More patient focused outcomes are likely to develop over time.

SO3: Difficult for me to answer as I don’t experience inspections and I haven’t seen any being carried out.

S04: In a way it does, the better a pharmacy does in terms of being innovative, implementing good services in the pharmacy, the better service the patient will receive from the pharmacy and the better image pharmacy will have. Yes, the standards will have the pharmacies achieved better.

S05: It probably does lead to more focus on the patient in combination with the inspection process. The new standards and inspection mean that pharmacists are more likely to assess what they do and consider trying new things to improve their service.

S06: I don't think so yet, I think that is a longer term process and it is not all down to the GPhC. We have done some work on patient safety and how we might share information in supporting teams in doing the right thing more often. I think if we rely on the regulator to getting people to think about care and the impact the changes might have on the care they are delivering to patients, I think we might be waiting a long time.

I think the GPhC are playing a part in that and rightly so, and I think consultation exercises, listening exercises and stimulating conversation/patient centred professionalism is a part of that. They are keen that stakeholders and associations get involved in that and promote that sort of change themselves. A particular challenge for pharmacies because regulation has been related to the medicines, until [...] started to get involved in GP inspections/pharmaceuticals, it was the only care profession that had an inspector for. That was originally to ensure that medicines made in the back of the shop were the nature and quality intended. Shifting from produce to service focus. Medicines and their use and not medicines in use. That is not a matter that should be left solely to the regulator to fix, as the regulator is not necessarily a leadership body.

S07: They are certainly looking to do that and within the classification system the pharmacies who score higher are the ones who are taking a wider view of the community and their contribution to the local health economy. I can't comment on how that is working in practice.

I would say through this evaluation and other work, the feedback will inform whether or not the standards are achieving that and the processes around them.

S08: No, GPhC approach is rather a supplementary aspect (as above).

Have the standards helped change a culture previously focused primarily on rules and compliance, towards outcomes, professional decision making and improvement?

S01: It is too early to say whether there has been a change in culture.

S02: Yes, current standards are better than old ones. Change has also been implemented by learning from others (i.e. within pharmacy chains).

S03: I think they have the potential to do that. I'm not convinced that one inspection will achieve this. It will take a number of iterations before we get to that point.

S04: Yes. Across the board all pharmacies are delivering what they have to deliver and the vast majority do and it should not be the case of just going to the pharmacy because a complaint has come through. So not because they did something wrong rather trying to put everything right at the beginning that those wrong things do not happen, so getting the standards right from the beginning.

S05: It is too early to say whether there has been a change in culture.

S07: Absolutely that is what GPhC tried to do and we would support that. I have worked in this for [...] years and don't underestimate the ease in which that can be achieved. It's good that the key bodies are supportive of that, but I would imagine it will take a while for every practising pharmacist and pharmacy area to fully engage with them.

SO8: They have made a change in a sense that they have made people start to think about what they do – the old “tick box” approach did not do that. However, people do not “do” yet – it is likely that they will change their practices with time - it is always difficult with you first inspection as it is a benchmark. With time pharmacies will be more familiar with the process, they might develop a professional desire to get better.

Are there any unintended consequences of introducing the new outcome focused standards for pharmacy premises?

SO1: NA

SO2: No.

SO3: Again I don't really have any evidence about this. But going back to the point I made about the involvement of the whole pharmacy team and staff being aware of the implications of their answers, clearly, there will be some pharmacists who will be coaching their support staff, especially as to what they need to say during inspections. However, we don't want staff to be coached, we want them to provide an accurate reflection of how the pharmacy is run. Support staff should not be asked to lie which could become quite common.

SO4: The way inspectors approach this. They would need to make sure it is not a culture of penalising people. The GPhC has said that they do not really care how the standards are been achieved as long as they are being achieved. It's up to the owner and the superintendent how they want to achieve those standards. It leaves it open for businesses to make up their mind until they achieve a particular standard.

SO7: I can only go by attending one of the stakeholder events and seeing some of the headlines – so I am not best placed to comment. There has been an issue raised about the length of time the inspection takes, there will be a balance to strike as there always between the length of time it takes and the benefit the pharmacists and its staff get out of it. You have to go for the shortest inspection time possible but balance it so the benefits reflect the effort involved.

2. Inspection

How far does the [GPhC's] approach focus on outcomes, drive improvement and is applied consistently?

SO1: I believe that the standards are applied consistently by individual inspectors, but the whole area of grading pharmacies is new (previously it was pass/fail) therefore there is some variation in how the inspections are graded.

SO2: It is set out very clearly especially with regards to outcomes.

SO3: The consistency in application is difficult to answer. However, because [...], I am aware that decisions are looked at across the board so that there is still some level of moderation across their decisions and across inspections/inspectors within and across regions. I am aware that this sort of work is underway to make sure that, when reports are ready to be publicised, pharmacies can be assured about a certain degree of consistency in decision-making within their region and across the country.

SO4: By having those standards pull together in terms of what is expected from the pharmacy and this is what you need to do to make the standards are achieved. And let the owner and superintendent quite free in terms of achieving those standards. It makes easier for pharmacists to be able to see what standards GPhC is looking for and to be able to demonstrate that. It is a good thing that have all those standard in all Great Britain.

SO5: I believe inspectors are now more aware of exactly what they are looking for during an inspection.

SO6: A while ago we were concerned that everyone was getting the same score, but when you look at the inspectors report it could be quite different. They could be the same and come out with different scores. That would suggest there was a lack of consistency in the very early days. Now everyone is pretty happy to say, we are learning, park it and talk to one another with a view to get it right. Taking everyone on a journey – the usual stuff.

They haven't got it right yet but it is changeable. We can't tell if there is great consistency at the moment with inspections. I would say at this stage I would not expect there to be.

If you have a large organisation with lots of pharmacies, they have a window into the inspectors and their behaviour and what different inspectors might be seeing and doing about essentially the same set of standards. It is something we have discussed on various occasions at all types of levels. We have a board director [...] who is effectively our lead through the inspection process, who has discussions at the next level down. Regular dialogue with the professional practice group. They have used it as their own sounding board. The direction of travel is good and things are changing. We are keeping tabs on what pharmacies are in what boxes, and we are seeing them move now. The review of the labels and thinking that through a bit is very welcome. Everything is moving in the right direction but they are not quite there yet.

SO8: As discussed above. It's better than the old tick-box exercise – it's more involving, encourages the provision of evidence to show what pharmacies are doing. So in that sense there is tailoring to outcomes, purely because you are thinking about the things that you do. But I am not sure that it is an outcomes focused approach particularly.

How do pharmacies experience inspections (e.g. how do pharmacies prepare for inspection; is notification in advance helpful)?

SO1: Pharmacies receive notification of a period in which the inspection will take place. The actual date of the inspection is unannounced. The inspector turns up on the day of the inspection and the responsible pharmacist will have to have to answer questions on the principles and provide supporting evidence. So they will be expected to have carried out some preparatory work. Pharmacy staff are also asked for feedback to provide paperwork and evidence on how plans are implemented and general feedback on the premises. The staff do not have to prepare for the inspection.

The inspections take longer than they used to – they take a lot longer than 2 hours now. The pharmacist also has to provide evidence which they never used to have to do. This means the inspection process is quite different for pharmacists compared to the previous system.

SO2: Since the inspections were carried out for the first time under the new approach, some pharmacies were anxious about the process. The second round of inspections will be experienced better.

SO3: There is a huge spectrum there. Those who see and continue to see inspections as a tick-box exercise are the most likely to be "shocked," especially due to the action plans that come out of these inspections. The more proactive pharmacies, on the other hand, will take time to digest the information and understand the standards and the desired focus on patients, quality and safety.

SO4: There is a mixed view. Some pharmacists have reported it's straightforward, they like the approach of the inspectors. And others pharmacies felt they have been put in a difficult situation because the inspection has been taken a long time and the staff has felt uncomfortable. However,

the approach has been ok, but one thing that the vast majority of people have issue with was the grading satisfactory. The satisfactory makes people very demotivated, because if you have not got an action plan to fill in when you get a satisfactory then you should be under a good grade. So for a vast majority of pharmacies to come under satisfactory does not portray a good image of the profession.

SO5: The inspection usually lasts about 4 hours, or half a day. This is double the time the inspection took under the old system. The inspection process now covers more topics and goes into much more detail on each topic. The pharmacist is now expected to prepare evidence to support what they are saying, and this has to be done in advance of the inspection.

There is also a greater involvement of the support staff in the inspection process. The inspector will check the staff awareness of policies. This gives the inspector a better understanding of what is happening in the premises. While the inspector is in the premises, they will also observe what takes place in the pharmacy to see for themselves if policies are being implemented.

SO6: Speaking generally, given we are still having conversations about some of the aspects we talked about, suggest we are not entirely happy and there are challenges. One struggle is that inspections can be very long and therefore disruptive. To have an inspection that lasts 50 or 100 per cent longer than expected can be onerous. Average inspection now 2 – 2.5 hours. Can take 5 hours and then raise nothing in the report. Happening less often – was a familiarity issue. Different inspectors with different characteristics. Judgment calls made at different speeds. Raised time consistently with GPhC.

Also the time you get to respond, plus GPhC does not always hit deadlines for its part of the process. That then impacts on your response time. Experience and practice has meant that the timelines have been amended.

Notification is not on our radar. As they want to see what normally happens and not what happens because someone knows they are coming. GPhC are looking to adopt more of a risk based approach. If a large company with 1,000 pharmacies has its processes in order then certain things are in the standards you would expect. If none of the pharmacies is running as intended, do you need to go to the other 1,000. Or will they learn over time that if you go to 10 per cent over a number of years then for those elements you don't need to visit every single one. The general acceptance is that the GPhC identify areas of concern or room for improvement, you then might have a visit sooner. Resources will be put into pharmacies that are seen to have room for improvement and no one will argue with that. It is logical but also if you end up with a poor rating you would want to put that right quickly and after getting a poor report would not want to be waiting for example 5 years to be reassessed. People want to take action based on reports.

SO7: Because I am not part of a pharmacy and have not been inspected, I cannot really comment on that. From my experience of the stakeholder event – during the inspection people will have a better understanding of the standards. That came out in the conversations, which is obvious really. If you have an inspection if you have not engaged with the standards before, then that is when you do.

SO8: Talking to everybody in the pharmacy is helpful. Also, to think about the evidence as a group, and not as an individual – in terms of multiples.

How helpful is the GPhC's inspection decision-making framework when thinking about inspections?

SO1: Not sure.

SO2: The majority of pharmacies have come under the satisfactory category but at the same time they have had the action plan implemented (again, the majority of pharmacies have). There is a need for a clearer explanation of what satisfactory means.

SO3: Difficult for me to answer as I haven't seen or worked with the inspection decision-making framework.

SO4: The main issue is that 90% of pharmacists have come under the satisfactory category. And some pharmacies have been asked to do an action plan to do, some other not. So the question is why are those pharmacies who have not been given an action plan to do are not considered good pharmacies?

Also the GPhC has also said that the excellent grade is a difficult grade to achieve. And so far only one pharmacy out of all pharmacies inspected has been given the excellent grade. What's the point of having an excellent grade if it's so difficult to achieve it? What can the GPhC do about that? The GPhC has said that pharmacies need to demonstrate that they are innovative and to go beyond. And many pharmacies are innovative and go beyond so it's demotivating when they finally have not got an excellent grade. The [...] does not want the satisfactory grade (e.g. you wouldn't put your child in a satisfactory school).

SO5: Not sure.

SO6: Don't know, don't have an answer. Not on list of big topics.

SO8: Very.

Does the level of awareness of standards change as a result of inspection?

SO2: Yes, it will especially be seen in the second round of inspections as pharmacies gain experience of them.

SO3: Not as much as it should have done. There are still some very bad premises out there.

SO4: Yes, people are more aware and this is the kind of feedback [...] received when the inspector comes in. Pharmacists did not envisage that inspector will speak to each member of the team or they would actually checked the backyard and all facilities that they have. The inspection is an eye-opener with the inspection of areas that are not visible to the patients. It's definitely an eye-opener in terms of the level of details they are going to.

SO5: Yes, as discussed earlier some of the standards only become a reality when an inspection happens.

SO8: There is a high level of awareness.

Do inspections help pharmacies meet the standards more effectively?

SO1: Definitely – inspections are taken seriously by pharmacists. It makes them up their game.

The pharmacists do not want to fail their inspection.

SO2: It is difficult to judge as there is no "before" and "after" data available yet.

SO3: I think we will start to see more people understanding and working more in accordance with the standards to help improve their business.

There is a slight problem in community pharmacy – it is this dichotomy relating to whether pharmacists are actually retailers or health care providers? The whole point of the standards is to push them towards them understanding they are health care providers.

I think that to drive greater compliance with the standards, we should ensure that perception, in particular public perception, of the community pharmacy is that it is a healthcare environment and therefore needs to be meet the standards to provide the best health care services.

SO4: I agree. It does help but it has to be done in a way that does not penalise individual (and have an impact on the motivation).

SO5: Yes. Every pharmacist thinks they are doing a good job before they are inspected, as it's natural to think, "I've been doing this a long time, I'll be OK". However the inspections make them think about this more closely and can lead to changes being made to meet the standards.

SO8: Yes, inspections are a useful way for us to demonstrate the standards that we are achieving. However, inspections are missing a guidance on how the grading can be improved. I.e. how to go from satisfactory to good. The inspection report can sometimes be a challenge – there is no obvious explanation about why a particular grade was chosen.

Which elements of an inspection – involvement of the whole pharmacy team, facilitating learning and good practice, collecting and agreeing evidence –are most important to support pharmacies to meet the standards and to improve?

SO1: The involvement of the whole pharmacy team and the inspector being able to observe what is going on in the premises (informally).

SO3: I think it's involving the whole pharmacy team. Traditionally, pharmacies have not been good at that.

Through this new inspection model, the GPhC wants to ensure that pharmacies understand that the whole team needs to be on board when inspections are announced and undertaken. The whole staff should understand why the visits are happening and what the consequences are likely to be in the event of non-compliance and why taking remedial action is important.

SO4: All three. The fact that the all team is involved is an important factor; gathering evidence is also an important factor.

SO5: The involvement of the whole pharmacy team is useful, as it helps to see if something has been implemented. Sometimes they might 'moan' about things that happen which the inspector might have missed.

SO6: Bit patchy at the moment.

SO8: Talking to the whole team.

How does inspection impact pharmacies, particularly those without action plans? Does it provide a continued focus for improvement?

SO1: The ratings of the inspection report work well. It can force them to focus on improvement. Previously all pharmacies passed or failed. But now it can "hurt their pride". However, this can impact pharmacists in 2 ways: they may see it as a driver for improvement, as they want to be rated good; or they may think they have put in a lot of effort for a satisfactory score, and think it is not worth the effort in the future. This is because the range for satisfactory is very wide, with pharmacists who are miles away from a good grade being rated the same as those who are virtually good.

SO2: See above – lack of "post" data. Focus on improvement is implemented via action plans and in the interviewee's experience the majority of pharmacies have action plan assigned.

SO3: You could argue that whatever rating you get, there will always be some level of improvement you'd be working towards and aim to achieve.

SO4: If the pharmacy has not got an action plan and it has not received a good grade, pharmacists need to know what areas have they gone wrong? And get a proper feedback. And if they do not get an action plan then that demonstrates that they are doing well in what they are doing.

SO5: It can be very little. Good pharmacies will be happy, and as they are good they will probably continue being good (as their approach led to a good inspection result), therefore the inspection will not change their approach. For those deemed satisfactory, it is such a broad category that it doesn't really stimulate pharmacists to try to improve. They will be disappointed to be categorised as satisfactory, as they will feel they do a good job. Having spoken to pharmacists about this they do not necessarily try to improve. There may be a role for another organisation to try to help pharmacists categorised as satisfactory to improve – maybe the professional and trade bodies.

SO6: An issue about grading has been raised. If you think by and large you're doing ok and when the inspector is doing the inspection things are vocalised as good, but then you end up as satisfactory. This will then be raised as teams find it demotivating. No areas for improvement, satisfactory rating, worked really hard but then did not get a good rating. Coming back to how the standards are written and that there is a learning to happen there because the standards have moved from products to patients. There will be a challenge in getting used to thinking about that. Still some challenges around what pharmacies do about patient centred care.

Are there any unintended positive/negative consequences of regulatory inspections?

SO3: Not that I've seen yet.

SO4: The negative point could be that profession fears to be penalised and to be put in a bad light which would have a negative effect. Just need to be careful that 90 per cent of pharmacists falling under one category does not look good. The positive consequence is that patients will go for extra miles to make sure that they have been delivered a great service.

SO7: I am not sure I can say very much more than what I have already. [...] For me it is much more about the general approach and it being proportional and better regulation and all of that.

In the context of the Five Year Forward View is there a way to make the standard more future resilient? The potential huge role that pharmacies can take in trying to realise that. Thinking about what is happening in local health and social care economies.

Thinking about the service development, the standards and any revision to the standards and the regulation process does need to support safe supply of medicine but also the clinical services public health contribution that pharmacies are making and will increasingly make. The regulation process needs to embrace all of that, which is part of the work I am involved in. We are making it clear that the GPhC's role in the regulation of pharmacies is not just about the safe sale of medicines but it is also about the delivery of high quality clinical services. We support that direction of travel and the standards within that.

In the activity that occurs in a typical pharmacy, whether that is flu vaccination or blood pressure monitoring etc. Core services ought to be regulated by the GPhC. GPhC needs service delivery moved, as otherwise they can end up with a gap and would then need to look to cover that gap. From [...] point of view, it has the most regulated healthcare activity of the four countries.

3. Action planning

Is action planning an effective intervention leading to sustained improvement?

SO1: I believe it is fair to think that the action plans issued will have some form of sustained impact, as the inspector revisits a short period after to check changes have been made. He feels it

is a powerful tool to go back to owners and say you need to change x, y and z and will provide good motivation. However, I feel the action plan should also include a description of what they were doing well, so that improvements in one area are not offset by deterioration in other areas.

SO2: Yes, but actions plans need to be made explicit in order to be effective.

SO3: I don't think the action plan is that effective. It is just a snapshot in time to be honest. People will follow the action plan originally but when they perceive that they've completed these actions, they will go back to their "old ways".

SO4: If inspectors come across pharmacies that really do well, there is no need for an action plan. But there is a pharmacy that clearly needs to be improved then obviously an action plan is required. But again it should be in a way that it does not penalise pharmacy and that the pharmacy has some time to action it rather than trying to fix something quickly and not getting any benefits out of it.

SO5: I am not sure. I feel some pharmacies just see it as a box to be ticked – we have an action plan, make a quick suggested change, reassessment and then just go about it how we used to for the next three years. This would be the path of least resistance. However, if the owner is fully engaged with the process and actually wants to improve the action plan will highlight the areas they need to focus on.

SO6: Broadly speaking yes. There is always the question of so what? Something that causes that conversation and thinking is a good thing. To my knowledge it is not an issue. People tend not to talk about things they are happy with. It is helpful.

SO8: The things our action plan focused on were minor issues, where improvement would not necessarily affect patient outcomes. I.e. administrative issues that do not affect patient safety.

Where an action plan is needed, are the right areas highlighted in inspection reports to focus on improving quality, including safety?

SO1: I feel that it does cover the areas that need improving but that it should also highlight some areas the pharmacist is doing well.

SO2: Yes, see above.

SO3: I genuinely haven't seen one. So I cannot answer that question.

SO4: It could be clearer. A lot of people are left unclear about what it means. [...] would recommend that those pools are clear so that people clearly understand what it is that they are being told. Also people have this fear, and despite the fact that it has been explained before, that the report will sign their life away. They have to get away from this fear factor when it comes to those reports.

SO5: I would hope so.

Does action-planning lead to greater accountability/involvement from pharmacy owners and superintendent pharmacists?

SO1: Yes, I feel providing the action plan to owners does motivate them to change practices.

SO2: Being required to have an action plan will make the owner and the superintendent address all those issues.

SO3: I think it matters a bit more in small independent pharmacies. If the owner of a small independent is on holiday, for instance, you would assume that they'd take on a locum who knows a bit of about the business and does not necessarily paint a negative picture during inspections. So the owner and locum would have established a relationship prior to the inspection taking place.

In large multiples, what you often see is that superintendents are only involved where action plans have been prescribed. They may not maintain that level of involvement once the action plan has been put into practice. This often results in a poor level of understanding amongst pharmacists or contractors who may simply not know when/how to resolve certain internal matters without support from the superintendent office. They could well avoid unnecessary action plans if they were to be more proactive.

SO4: Yes it does when obviously the pharmacy has some shortcomings to address. Being required to have an action plan will make the owner and the superintendent address all those issues. But again it has to be done in a fair way.

SO5: Depends on the owner, as described above. The standards should increase the accountability of the owner, as the standards make clear where the buck stops. However, if the owner does not want to engage with improvement it does not lead to greater involvement.

SO6: No I haven't. Based on false premise – have been told that or am under the impression that some of those in the larger corporates ignore messages from Inspectors. I think the reverse is true, dialogue with a larger organisation results in them putting changes into motion – things tended to happen quicker. Due to brand and reputation, the bigger they are the more likely they might take action on an improvement notice. There was a feeling that the independents were 'picked on' by the old regulator. Not aware of it, the issues were different to the issues everyone assumed they were.

SO8: If it is something you never thought of, then it could potentially increase accountability but it depends on an issue. Where we had actions plans, they concerned maintenance issues within pharmacy but the 20 days was not enough to finish the work. So sometimes there is a bit of difficult to complete the action plan within the timescale given.

Are there any unintended positive/negative consequences associated with action plans?

SO2: Nothing more to add.

SO3: That's a difficult questions for me to answer.

SO4: The negative consequence would be that people get demotivated because of the time it takes to do it, because of the pressure of dealing within a certain amount of time. The positive would be that if there is a pharmacy that needs to improve things then having clear, outlined documents in terms of what it is they need to improve on, will have then to address all those issues. But it has to be done in a fair way.

SO6: No – there have been anecdotal comments from people saying they have found it more helpful than they expected. Some hold the view that 'everyone is out to get you' or one error and 'you will end up in jail' but actually you have to do something extreme or have extreme circumstances conspiring against individuals. I think that is not about bad practice, overzealous regulation, it is just difficult circumstances and the wrong view taken and everything escalates. Even the example from 5 or 6 years ago that everyone talks about in terms of how regulation should not happen – the pharmacist was "acquitted" or the prosecution did not occur but the pharmacist took herself off the register as it was such a bad experience. People remember that, and people see it against the backdrop of prosecutors hiding around every corner and inspectors ready to catch you out is what they are told constantly by organisations over and over again. People are fearful.

4. Reporting and publication

Does the provision of inspection reports and ratings provide an incentive for continued focus on quality provision of pharmacy services and improvement?

SO1: It can. As mentioned above it can either drive a pharmacy on to constantly improve service, or it can lead to apathy as the satisfactory band is too wide.

SO2: Yes it does. It has to be done in a fair way and we need to get rid of the satisfactory.

SO3: We need to get the terms of these ratings right first. I think ratings have the potential to adversely affect how people use them if we don't get the terms right.

SO4: Yes it does. It has to be done in a fair way and we need to get rid of the satisfactory. It will not give a good image of the profession, demotivate a lot of pharmacies.

SO5: It can. As mentioned above it can either drive a pharmacy on to constantly improve service, or it can lead to apathy as the satisfactory band is too wide.

SO6: Fair to say lots of people still say why is this going to happen. I am not convinced that they have got this right yet, nor am I happy with what happens if I get a bad result and how long that will sit on the public record. If I have an improvement notice, and I am uncomfortable with that - what is the reason for it. That is a key thing that has not been resolved. People can't understand why it is being done, as the whole [...] situation, duty of candour that sort of thing has passed them by. They have their head down in the day job.

There is still work to do to explain why it is being done and its impact

SO8: Need guidance regarding grading – there is clarity regarding what needs to be achieved to obtain a certain grade but we disagree with the current grading – the vast majority of pharmacies receive satisfactory – the term itself implies just about ok. We think that anybody classed as satisfactory without an action plan should be classed as good. Anybody as good should be classed as excellent. There should also be satisfactory with an action plan and good. I.e. there should be four terms.

Feedback concerning the proposal to publish inspection reports and ratings

SO1: This is a very interesting topic – are the reports in the public interest and will it change public behaviour? Customers can already vote with their feet if they don't feel a pharmacy is offering a good enough service. I doubt that publishing these reports would have a great deal of impact on the public as they will already use the best available pharmacy rather than one offering a worse service.

The reports might be of use to other health professionals and the advice they issue to their patients or how Local Health Boards or GPs are willing to engage with pharmacies with a satisfactory rating. Therefore it could potentially have business issues for the pharmacies.

SO2: It is a very good idea. However, it will need to be done in a fair way with the use the right language (around the definition of satisfactory, for instance). Also, what about the confidentiality around the information included in the summary reports?

SO3: I think overall people understand we are in an era of transparency and these sorts of things are going to happen. Pharmacies with good ratings will definitely want their ratings to be pulled out in the public domain. But the same may not be true of pharmacies rated satisfactory or poor.

Also, there's a judgment to be made about the inspections – especially about whether to publish the report in its entirety or just the executive summary. Maybe something in the middle – the rating alongside some information explaining the rating.

SO4: In principle, I agree with the publishing of report however it will need to be done in a fair way with the use the right language and the right grading mechanism to be able to do that in a good way. Otherwise, it has got the potential to demotivate people and put the profession in a bad light.

SO5: There is no impact at the moment. However, it will become interesting if the GPhC decides to publish. The publication could lead to pharmacies losing business. This would cause disquiet among pharmacists, and it is not clear what might happen.

The GPhC need to be very confident in the reports they publish. It may require sending the inspectors on more training to ensure complete comparability between decisions made in reports. If they could rely on the complete comparability of the reports they would be in a stronger position to publish the reports.

There is also a debate about what should be included in the reports and what is in the public interest. It would also need to pass the plain English test and not include too much technical language. Also how the information is used by the public – it is easy to see how it might work in more urban areas, but what about rural areas where patients don't have a choice about their pharmacy – do they just have to accept that it isn't up to standard?

SO8: We have a few concerns – the grading needs to be sorted, and once the grading is changed anybody who was assessed before their report should not be published (as their grading would not align with the new one). The second issue is that if somebody receives satisfactory or poor, when that's published, not only will patients think that the pharmacy is not up to standards which may encourage the new pharmacies to open – but NHS cannot afford new pharmacies (and doesn't want to see those). But NHS would have a difficulty in refusing applications to open a new pharmacy with an aim to replace the ones graded poor.

Reports need to be published in the form of a summary, and/or a full (but redacted) report should be made available upon request. Need to be careful what information is published – i.e. for pharmacies that dispense a lot of methadone, revealing too much information might expose it to risk of crime.

5. Other

Any other points the interviewee wishes to make, including areas for potential improvement.

SO1: The frequency of inspections should be proportionate to the risk from the pharmacy. The inspections should also not take place on a fixed three year window, otherwise pharmacists "will rest on their laurels for two and a half years before the threat of inspection comes round again." It should be more random on duration between inspections.

SO2: The terminology of satisfactory can be improved by, for example, looking at how other regulators have defined it, and also their experience of it. How did GPhC come up with this term?

SO4: I have an issue with inspections and inspectors not having a consistent approach to the inspection and there is an element of the personality that would play a role in the way they inspect. There is to be a greater emphasis on ensuring that there is a consistency across the board to inspection. [...] hopes that the grading mechanism can improve to make sure it works better for the profession and the way pharmacists are portrayed.

The questions were clear enough want to understand a bit more the next steps. Would you be sharing your findings with the GPhC? How many people in total are you interviewing? How many associations are you interviewing? I would encourage you to speak to people who have been inspected.

SO5: At the moment, the direction of travel since the introduction of the standards seems to be good. There was a “bumpy ship” for a while as people got used to the new standards and how inspectors were going about things.

There are still some things that could work better, but these could be done by professional and trade bodies.

SO6: Keep talking, keep listening and keep supporting other organisations’ attempts to help colleagues understand the process, very important. It continues to be the case that the process is collaborative as can be. Changing the view of the culture of the regulator will not happen overnight, as people have a view based on what has happened in the past. Have to keep working at it and have to demonstrate it is different. People should feel comfortable with the outcome and that the outcome arrived at is just. Issues continue with broad assessments with pharmacies needing no improvement and some needed improvements but with no explanation as to why that has happened. People like detail and like to know where they stand. It needs to be seen to be right by the people who are being regulated.

The figures are moving, it is low, 70 per cent currently satisfactory, it is still hard to say what satisfactory looks like and what good looks like. We have some kind of standard for what standard means and we can describe that, so for example for this box here if you do a bit of this and a bit of this you’ll be in this box here. There needs to be a bit of a well if you stop doing this you will be over here etc. Until we nail that down and also what patient centeredness means, there needs to be consistency. The proportions in each rating are shifting a lot. Until there is consistency we would be reluctant to see that information out in the public in detail.

SO7: The GPhC is a regulator for Great Britain and therefore covers 3 countries and so some differences are observed. The delivery of NHS services in the 3 countries is a devolved model. It needs to continue to work closely with the 3 countries so its regulatory approach and framework enables what the 3 health countries are trying to achieve. They are structured differently – Scotland is an NHS managed system, England is very much a commissioner provider highly regulated approach because of that removal of the command and control approach I suppose.

From my view GPhC are very clear about their role and responsibilities but also very engaging of pharmacy interests and patients and the public

SO8: The main positive is that it does start to encourage people to think about what they do.

Annex 6 Notes of depth interviews with GPhC inspectors

1. Setting and monitoring standards

In your view, do the current GPhC standards set out clearly what a pharmacy needs to do to deliver effective patient care? If not, what could be made clearer?

Inspector 1 (I1): I think that the standards for the purpose of inspections overlap too much in certain areas making them a little unwieldy to administer during inspections. For example standards 1.1 and 1.2 talk about managing risks in a very similar way. Other examples: 2.1 and 2.2 both talk about having adequate staff with the appropriate skills; standards 4.2 and 4.3 are both about managing services safely and effectively are very similar. I think all of these standards could be encapsulated within one standard. I think merging some of these standards will make it a lot easier to manage without actually losing anything. Additionally, merging some of the standards could allow us identify risks much more easily because we would be able to focus on the areas that we are most concerned about during the inspections. We would not have to worry too much about gathering evidence about every standard. Something the current model requires us to do. I think some slight re-wording of some standards could also be useful – 1.6 talks about ensuring that “all necessary records for the safe provision of pharmacy services are kept and maintained” – I think the word “all” implies that the inspector should go through each and every record to verify that they are being maintained. I think that one could be broadened out a little bit more and offer more flexibility to inspectors.

I2: They can be effective but how they are interpreted may vary. While we are trying not to have a checklist approach, I think some pharmacy organisations are inevitably developing their checklist approach to get through the standards (because the standards are so broad plus pharmacies want to ensure they get a high grading). That checklist is used to go through the inspections as good as possible rather than focusing on patient care. This is because of the grading system in place.

I3: I'm not sure that they do. As with any new process or benchmark that is put in place, it is taking pharmacists a bit of time to understand what they need to do to demonstrate they comply with the standards. What's happening now is that they are talking to one another, discussing with those who have had inspections and probably creating their own “checklists” of what they need to do to demonstrate they work in accordance with the standards. More guidance would help increase understanding of what needs to be done to meet the standards.

I4: I think they do - they are quite clear and explicit on what is expected of pharmacists to have in place in their pharmacy. There is some overlap between standards but they do clearly state what sort of responsibility pharmacists have and what they should do to ensure their pharmacy is safe.

I5: The standards are not intended to be regarded as “black and white” but certainly they are a vital tool to ensure that patient safety is maintained and delivered. So they are very effective in that way. And I've seen, in the short time they have been used, that they have improved safety. The standards themselves don't really need to be made clearer – they

shouldn't be prescriptive or black and white. The information and guidance around the standards and how to achieve them, yes, that's possibly not as detailed and helpful as it should be. But then other organisations – such as the NPA - have developed toolkits to help the teams acquire a clearer understanding of the standards.

The only exception – I do find a lot of repetitive elements within principles 3 and 5. They could quite easily be merged as one principle. Both principles focus on pharmacy premises (how clean, tidy premises and machines are, etc.).

16: I would like to first raise a few general points about the standards:

- it's down to the individuals/organisations to show compliance with the standards; however when it comes to certain individual standards, there is a lot of inconsistency in presentation and ease of interpretation – for instance, the standards associated with principle 1.5 (on having appropriate indemnity/insurance) are very specific. Either you have insurance or you don't. It's a binary sort of standard. Conversely, standards under principle 2 (e.g. standard 2.4 which talks about culture of openness) tend to be vague. I think these standards ought to be made more explicit. They could be rewritten to allow you to determine in a clear manner whether the pharmacy is achieving it or not (a bit like the binary standards under principle 1.5). As an inspector, it therefore becomes difficult to guide the pharmacy team on what they should be doing to achieve an "excellent" rating. We cannot tell them for sure what "excellent" ought to look like.
- there is a lot of subjectivity underlying the inspections – take principle 3 (on cleanliness) for example. My idea of cleanliness is completely different from that of my partner's. This could be a good thing but could also be problematic leading to inconsistencies in inspectors' assessment and final judgement/rating of the quality of the services offered by a pharmacy.
- some of the standards overlap – e.g. standards 2.1 and 2.2 are very similar.
- I have also some concerns as regards particular principles. Principle 4 (on medical devices) is, in my opinion, not prescriptive enough. I understand we don't want the standards to be too prescriptive but there should be a minimum level of guidance. This is problematic as registrants are not clear about what they need to do to comply and inspectors cannot demonstrate how this principle is to be achieved in practice. So, I think a key issue is that, as an organisation, we do not provide enough guidance to our registrants.

On the whole, I would say that the prototype model (based on the new standards) has the right intentions to move away from centric dispensing and towards increased delivery of clinical services. But we have to be a little bit more prescriptive to ensure registrants understand their duties and can abide by the standards.

17: No, the standards do not set up what the pharmacies need to do, they set up what they need to achieve. This is an important difference.

I8: The new standards provide a very good framework for pharmacies. They cover similar topics as the previous standards (although in a different way) so pharmacists are still aware of the types of things they need to be doing (it hasn't involved large changes in activity). They are less prescriptive in their nature now, which allows some innovation, allowing pharmacists to think, "My way of meeting standard X is good for patient care because...". The new standards are more about risk management, procedures and approaches to topics, rather than a more "tick list" approach in the previous standards. They provide the topics that need addressing, but also provide freedom for the pharmacist to think how to meet the standard. I believe that the standards are a good starting point for regulation. They will probably need slight modifications in the future (as standards and requirements move with time), but they cover the right topics at the moment and are clear to pharmacists about what they need to do to ensure good quality patient care.

I9: The structure of the standards is fine. The five principles, and what they include is clearly set out. However, the problem with the standards is that they are very high level and don't include any examples of what a good approach to meeting each standard is. There is no information on how to meet any standards. This used to be included in the old standards. Initially, it was thought that the professional bodies might provide this kind of guidance for pharmacies. However, this was an assumption, and no instructions were given to pharmacies to provide any guidance. Therefore, there is nothing available except for the guidance given under the old regulatory system. This is OK for some standards, but it doesn't exist for other standards. He is unsure if it is the regulators role to provide this guidance, but some should be available for pharmacists from somewhere. This change from the previous system, where pharmacists were "spoon fed" information on how to meet the standards requires a culture shift.

I10: I feel that there are gaps in the standards, around independent prescribing and internet sales. This is because this is a newly developing area, but the standards need to be dynamic and cover these issues. One issue with an outcomes based regulation system is that "it is very easy to identify when things go wrong, but it is more difficult to see when things are working well".

Based on the inspections you've carried out so far, what can you say about the level of awareness of GPhC standards among pharmacists and pharmacy professionals? How could awareness be enhanced?

I1: I think awareness of the standards is probably inconsistent. I typically ask, at the start of every inspection, what the pharmacist knows about the standards as well as the inspection model. I've noticed that it is "mixed" – some pharmacists know about them, others are fairly familiar with them. There are also some who don't know much about the standards. To improve awareness of the standards, I think a more active approach to promote the standards would be helpful – e.g. face-to-face meetings with our stakeholder groups such as the [...] could help increase understanding, especially at local level. I think we rely a bit too much on individuals referring to websites and publications. I think we should be seeking them out more.

I2: In larger organisations awareness is very high (as the sharing of the knowledge is easier) and it varies amongst smaller ones. In general the level of awareness has increased over time. Generally there is now fairly good awareness.

I3: Some are more aware than others. I think the multiples have provided their staff with more training and guidance. On the other hand, I think the independent pharmacies look up to us for advice and information. When we first started the new inspections, there were some webinars providing more explanation around the standards. Maybe it's a good time now to have another push at promoting the standards and check how pharmacists are feeling about the new standards.

I4: I think it varies. But over time, it seems that pharmacists are becoming more aware of the standards and the new inspection model – they are attending more meetings and seminars that are helping to enhance their awareness. I feel that pharmacists better understand the standards and what sort of things they should be doing that would help them meet the standards. I know that a lot of the inspectors and many other members from the inspection team have been attending seminars at external companies to help raise awareness and I think that has played an enormous role in helping pharmacists understand the standards better.

I5: It was not very good at all at the beginning. What I can say is that, in the first eight months or so, understanding of the standards was pretty poor. However, since the start of the New Year, I've seen that this has improved. The large multiples, in particular, have done a lot of work in raising awareness amongst the teams – having training sessions, etc. That's certainly paying off! But even amongst the independent sector, those pharmacies that have always been proactive and keen to focus on patient safety, they are a lot more aware of the standards and the information available. We're still however having “blank expressions” from certain pharmacists regarding certain standards, especially pharmacists who haven't (historically) really engaged with the GPhC in its former role with regard to dealing with standards and best practice. That's some sort of a historical behaviour and that's often difficult to change. But overall, I'm certainly satisfied - there's a lot better awareness out there.

I6: Registrants tend to say they have a good understanding of the standards but, honestly, the evidence suggests they don't. What complicates things is their interpretation of the different principles. Additionally, a growing problem is that registrants are using the decision-making framework as a check-list. They tend to even paraphrase certain areas or parts of the decision-making framework that have been classified as “good” or “excellent” to prove they have to be rated in a similar fashion. The real issue though is that they cannot always provide the necessary evidence, owing to a different interpretation of what the inspection framework is aiming at. However, consulting the framework may not be right. The key problem is that the framework was developed before the prototype model was rolled out. Since then, it has not really evolved. Things have changed and pharmacists ought to be more creative.

I8: The level of awareness of the standards is high. However, I believe that this is because inspections are “daunting” and pharmacists research what they need when an inspection is due. Inspectors take information about the standards with them to inspections, to give to

pharmacists if they do not know about the standards. However, I very rarely have to provide any of this information. I don't believe that awareness needs to be enhanced due to the high levels of awareness among pharmacies. There was a large amount of coverage about the standards from the professional bodies, support networks and in the trade press when they were introduced. I also believe that information about the standards are disseminated through pharmacy chains and in the pharmacy community (pharmacists talk to each other).

I10: The level of awareness of the standards is fairly high.

Do pharmacies use the GPhC's standards and other information available on the website? If so, how and why?

I1: I think it's inconsistent. Some may have, others not. Some have paper copies of the standards as well. Some work for large organisations and there are people internally to brief them on the standards and how they can meet the standards.

I2: They use the standards but are not using the information available on GPhC websites so much – they use more of NPA's websites and RPS. The information on GPhC's website does not give much guidance while information available on other websites is more direct and approaching a checklist format.

I3: It varies a lot. Some pharmacists are very keen to do well so they consult the NPA. Many also use our website. But it's not everyone, unfortunately.

I4: I've been in to pharmacies where pharmacists have visited the GPhC's website before inspections to have a look at the standards and print them out. What I equally found though is that many pharmacies use external sources as well – such as NPA's material on inspections and standards. However, some pharmacists are not aware of the existing material and say they will consult such information after the inspection.

I5: It does vary. I do see a lot more of people having gone to the website and they will have printed out the different documents that are available, with regard to the new inspection model and the new decision-making framework. If they are an NPA member, they will also have obtained the NPA's guide and that would be obvious during the inspection. Overall, I would say pharmacists have a better understanding of the standards and although they do not provide verbal confirmation that they consult the GPhC's website of other guidance published by other organisations, I would assume they are because understanding than it was.

I6: There is no guidance on how to meet the standards from the GPhC – i.e. there is no real guidance on safe-guarding or staff numbers. There are some other forms of guidance documents that seem to have popped out over the years – for example guidance for responsible pharmacists. But nothing specifically related to the new standards. The only relevant piece of information available to registrants (and also available to the public) is the inspection framework. But, as I've said before, this was developed in the latter half of 2013 and has not progressed much in style or practicality. I think GPhC seems to be lacking in guidance. The attitude is that guidance is something other organisations ought to provide.

I7: Not as many as they should. Some people have but it's not universal.

I8: I have never asked where pharmacists find out about the standards.

I9: Yes, that is where I suspect most pharmacists access the information on the standards, although I do not question pharmacists on where they get their information.

Do pharmacies consult information provided of relevance to the standards, for example, by the Royal Pharmaceutical Society or National Pharmacy Association? If so, how and why?

I1: Yes, as I've said before, it tends to be inconsistent.

I2: Yes.

I4: I think a lot of what pharmacists are currently doing is part of the standards, but many pharmacists may not be associating what they do with the standards.

I6: My understanding is that these organisations may provide some information to their members. However, it's their interpretation of the standards, not the GPhC's.

I7: They go through a variety of all these and also the [...]. They also got involved with commercial organisations. The GPhC is setting the standard but those alternatives are more focusing on the practical things that they could do.

I8: I have never asked where pharmacists find out about the standards.

I9: Yes, particularly when they are looking for examples of what works well, or what is good practice. Modern examples of this don't exist, but the examples from the previous regulatory system still exist. I feel pharmacists are still accessing and using these.

I10: See my response above.

Do pharmacies actively engage in meeting the standards, or are they merely seen as a reference tool for inspections?

I1: I don't think that's the case. I think, if it was, I would probably be seeing a lot more preparation. There are a few cases where pharmacists are able to provide evidence against each standard. But it seems to me it's more the opposite. I tend to lead the conversation. I'll provide them with examples of how to meet the standards and ask them if this is what they do on a daily basis. In general, they tend to rely much on these examples to show they are compliant. They are not really thinking outside the box. By the looks of it, pharmacists seem to be quite content to rely on examples inspectors suggest to them as opposed to thinking about and providing compelling examples they can draw from their day-to-day work at the pharmacy to show how they achieve compliance.

I2: Yes, they do try and meet the standards (in my experience most pharmacies are trying to meet the standards).

I3: I think staff at a pharmacy is not probably thinking about meeting the standards- the standards are just part of their day-to-day job. As pharmacy professionals, that's what they see themselves as there to do – to assist patients and to have a higher standard of service every day. A lot of pharmacy staff do go the extra mile (although it is often difficult to capture that during an inspection) to provide the best service to their patients.

I4: I think a lot of what pharmacists are currently doing are part of the standards but many pharmacists may not be associating what they are doing to the standards.

I5: I don't get the feeling standards are just seen as the basis of a tick-box exercise. The feedback I get when I'm chatting to pharmacists and their teams, they think that these standards are right and should be in place. They also agree with the outcomes the standards are aiming to achieve in that services are to be provided safely. They clearly see the link between standards and outcomes. I would say that the willingness to meet the standards is genuine rather than to please the GPhC. Of course, there are others who are more concerned about the ratings and want to be seen as the best. So here, standards could indeed be regarded as an inspection tool only, as a means to get a "good" rating. Overall, what I generally see is that, pharmacies were already doing what's prescribed by the standards anyway. The inspection reports provide them with the reassurance that what they've been doing is right and also provide them with the incentive to carry on as they have, especially where they've had "good" ratings. Where they were less good, they have an incentive to make necessary changes achieve better ratings at the next inspection. Those pharmacies where they have a really good understanding of the standards and outcomes will strive to be good across the board consistently. Unfortunately, there will be the "odd" pharmacy and I've noticed that even before the new inspection style, some pharmacies will literally "dip" and they will just keep on doing as they were and then next inspection, they may take action to improve, if asked, but they may not have the engagement, desire or competency to maintain that level. Historically, there have always been exceptions.

I6: The majority like to be told what to do rather than demonstrating how far they are proactively meeting the standards. The new model is, however, pushing for a culture change.

I8: I feel that the majority of pharmacists use the standards for inspections. This is because the standards are similar to previous standards, so pharmacists already feel that they are providing a service that meets the standards. Pharmacists use the standards in more detail when an inspection is due to ensure they have evidence that they meet the standards, as no one wants to be rated as poor.

I10: I am not sure if pharmacies are actively engaging in trying to meet the standards. "Good pharmacies have carried on being good".

Do the standards encourage pharmacies to focus on patients and users of their services? If so, how?

I1: The word “services” appears a lot in the standards. I think because there are too many standards, that sort of idea gets lost a little bit. I think if they were refined a bit more, it might be easier for pharmacists to understand that we are primarily inspecting on behalf of patients. But because of the number of standards and the sort of diverse nature of them, the idea gets “lost” a little bit. I think the problem as well with them being called “premises standards” is a bit of a “red-herring.” The standards are not all about premises – there’s just a small section on premises. So maybe this is a bit misleading for pharmacists and their teams.

I2: What I find interesting is that some individuals very much focus on patient care (although probably a minority and in smaller organisations). These meet our standards by default. But in most cases, it’s the other way round – they are taking a more checklist approach.

I3: I think the new approach involves the whole pharmacy team. That in itself places more responsibility on counter assistants. I think the new approach and the standards have just expanded interactions with patients. This “patient-centred” message is largely getting across I believe.

I4: The standards focus on the provision of safer services and practices to patients. However, I’m not convinced that pharmacists associate standards with helping them provide a better and safer service to their patients or users of their services.

I5: In my view, the standards are essential in addressing the key message from the GPhC about better patient outcomes. I do think the standards focus people’s minds on outcomes, especially the patient experience. The standards are not just about dispensing but they focus much more about thinking about the person receiving a particular service. And also the standards make the teams realise the importance of their roles and responsibilities and I suppose, in a way, probably enjoy their work more. They get to see the “bigger picture.”

I7: Yes, the standards are patient focused.

I8: In combination with the inspection it does help to focus pharmacists on the needs of the patient, as pharmacists do want a good rating from the inspection. The inspections also help to change pharmacists practices (either before the inspection or because of feedback/action plans they receive).

I10: I am not so sure on this point. Pharmacists are primarily a business. “Pharmacists will do things that will make them money.” I believe that the majority of pharmacists are run as businesses, and will focus on that first. However, providing a good service and focussing on the patient is a way of ensuring a loyal customer base and developing good relationships with commissioners and GP practices. So they probably are focussed on patient outcomes, but because of the effect it has on their turnover/profit, not the standards.

Have the standards helped change a culture previously focused on rules and compliance, towards outcomes, professional decision making and improvement?

I1: I don't think the standards have driven this culture yet. There are very few occasions, if any, where pharmacists will give me evidence which clearly demonstrate an outcome-focused approach. Their evidence is principally process-focused. They don't necessarily provide examples of the impact(s) of their services or the quality of their services on patients. I think, fundamentally, instead of overly relying on the ratings system to try promoting an outcome-focused approach to pharmacy services, this notion should be embodied in the actual standards so that pharmacists understand that it is a fundamental part of meeting the standards. There should be more description as part of the standards about how to be more outcome-focused which I believe is currently lacking.

I2: Yes

I3: Most pharmacists have genuinely always put patients first. For a long time, pharmacists have had to follow the law (e.g. control drugs, etc.) and do what's legally correct. I think some of the standards that are really producing a change in community pharmacy practice are mostly the standards around the conditions of premises. A lot of the pharmacies I've been to are rethinking about how to improve the conditions of their premises, maybe by making them safer, more suited to their patients.

I4: That's difficult to say I haven't got anything to benchmark current performance against. But having said that, I'm not sure standards have achieved this yet. Nevertheless, I'm sure that, as the new inspection model becomes more established and we continue to carry out more inspections, pharmacists will understand it better. I would think that those pharmacists who have undergone an inspection under the new approach, they sort of understand our move-away from the older style to the newer style. We should hope that they will get a better idea and view of the standards which will hopefully influence future provision of their services.

I5: What I've said before sort of covers that. I think that moving away from the old style – which was a more prescriptive approach – is much better. We want to see people embrace the different tools they have available (e.g. IT tools) to deliver the best service they can to their patients. I think smaller independent pharmacies / smaller multiples could still be struggling with this concept of what's available, maybe technology-wise, to improve services – i.e. moving away from the simple dispensing activity and see what else they can offer to patients of their vicinity. That is something really slow to take on board. However, again, the standards and the way we talk to teams about linking the standards to patients' experience could help improve that element where pharmacies are more engaging with their local community and move away from a purely dispensing activity.

I6: The majority of the community pharmacy business is still dispensing. There are certainly other services coming in – e.g. providing advice, providing supplementary prescribing, carrying out Medicine Use Reviews (MURs), undertaking health checks (by appointment), etc. However these services do not make up the majority of the community pharmacy business. Not for the moment. But the reality is that the provision of services in a community pharmacy setting is heavily constrained. Contractors require commissioning authorities (e.g.

local councils) to commission such services. They may, of course, offer these services privately; however they would need funding from the NHS.

I7: Yes they are changing the culture but slowly. Maybe people are really wanting to have an inspection before they fully understand the scale of the change. They should be more aware and more on the front foot. The inspection is a very good process for educating and almost training people. However it would be preferable if people have earlier access to the information.

I8: The standards do now focus more on risk management, procedures and approaches to topics which allows more freedom for pharmacists to focus on innovative approaches. However, pharmacists were already focussed on patient outcomes under the old system of regulation.

I10: Maybe this has happened for some pharmacists, but in general I am sceptical that it changed the culture much. As above, I feel the driving culture in the sector was a business culture. They comply with the rules and standards in the best way run a sustainable business model – they don't target a specific culture and assume that a sustainable business will come from it.

Are there any unintended consequences of introducing the new outcome-focused standards for pharmacy premises?

I1: I wouldn't say there have been significant changes as yet. It seems that this message on being more outcome focused is not being communicated enough or pharmacists are not picking up on that. If the standards were principally outcome-focused, we would have a lot more "good" ratings out there. Because, generally-speaking, "good" ratings are awarded if the pharmacy can provide compelling evidence that their service is highly outcome-focused and not merely safe for the patient.

I2: There are no unintentional consequences for patients but the labels and the grading system that we use means that, for example, the better the pharmacy is, the longer I spent on its inspection, and that is not a good use of my time. I should spend less time on them, and more time on those that are not so good (and/or use this time to perform more inspections). It takes so long because pharmacies collect so much evidence trying to meet the standards. This is perhaps the unintended consequence of the new approach. If we didn't have the labels (and only had met the standards/did not meet the standards approach), you could write the report much quicker. There is a scope for improvement there.

I3: It's not something that has been mentioned to me. Difficult for me to answer.

I4: I can't really think of any.

I5: I feel very positive about the standards so it's difficult for me to think of anything.

I7: One, it takes a lot longer and this is a challenge for both for the inspectors and the pharmacists. Two, they have been surprised by the rejection of the term "satisfactory". It

seems to be a strange distribution of results, 90 per cent or 95 per cent of pharmacists were “satisfactory” and this has not been well accepted by the profession – probably quite rightly.

18: More emphasis on safeguarding, particularly around vulnerable adults. This has helped with providing assistance to older people to take medication, check on wellbeing, etc.

2. Inspection

- How far does the [GPhC's] approach focus on outcomes, drive improvement and is applied consistently by the inspectors?

I1: The GPhC has had a few stabs at trying to define what “outcome-focused” means in pharmacy practice. The GPhC's drafted and published a couple of times what pharmacists should do to achieve good ratings and has provided some examples. But I think because these guidance documents for inspectors are written in such a “high-level” way that for most inspectors, including myself, it is difficult to relate them to any practical examples that we see in the pharmacy. Similarly, although pharmacists may have read these documents (e.g. the decision-making framework), they find it too vague, too conceptual and do not provide them with no clear direction as to what outcome-focused examples they should provide to achieve good ratings.

I2: Yes, I think it does but the tricky bit is to direct the pharmacist towards the outcome based direction rather than an evidence-showing approach. Especially for them to focus on patients – I am not sure we have managed to send this message across. Our focus is still too much on the processes where we should focus on what the outcomes are. Sometimes processes seem good (on paper) but the actual outcomes might not be (which then suggests that something is not working right and therefore the processes might not be as good as they seem to be). We need to define/develop processes that look at outcome/outputs more.

I3: What most inspectors would agree on is that there is a lot of pressure for time. So we need to be as efficient and productive as possible. Asking open questions to help gather evidence we are looking for is the sort of approach many inspectors have undertaken. I think there is a bit of consistency in what we are looking for. We probably are not as consistent as we should be when drafting reports – I've seen colleagues of mine reporting on slightly different things than me in their reports. But maybe there is some consistency across inspectors as regards certain standards and what sort of evidence we ought to gather and how we should report that evidence.

I4: The style of inspections has moved away from just looking at paperwork. I think that talking and engaging with pharmacists actually make them see why they should be doing things in a certain way and what they should do to improve and provide better and safer services to their patients. On consistency, it is hard for me to comment on. I haven't been out with all the inspectors but generally, the ones I have been out with took the same approach to inspecting pharmacies.

I5: I would say that, with the new inspection model initially, it possibly wasn't easy to help pharmacists achieve patient-focused outcomes. This was because of the way we were asked to get the evidence, embed it into the report on-site and ask the pharmacist to read

through the report of the evidence we had gathered and to also do that in a very strict period of time. This meant that you were possibly at risk of losing the key objective of patient-focused because in your mind you were tick-boxing and saying, “yeah, I’ve got to be out of here in 2-3 hours so I need to make sure I cover every bit of evidence so that I can go through it with the pharmacist and have him/her agree.” So it was all about being thorough and not missing out any bit of evidence. But having that distraction of thoughts in your head, you’re bound to miss or not completely be engaged with that outcome you wanted to achieve from testing compliance with the standards. With the new model, on the other hand, we’ve changed the process and we no longer require the evidence to be read by the pharmacist. I feel now I can communicate more with the team, especially on what I’m observing or asking the staff how they do a particular task. On the point of consistency: as an individual inspector, I don’t get to see that many inspection reports. But the impression I get there is variation amongst the teams. I’m a [...] so I get feedback about the inspection process. They query now and again a colleague’s judgment against a standard that’s never had to be addressed previously. I believe that maybe there was something unique happening at this pharmacy at the time prompting the inspector to judge that compliance to that standard “poor” or maybe that inspector just has a particular interest in certain standards and has high expectations with regard to compliance with this particular standard which the rest of us don’t. This does not really help in terms of consistency. It is then a matter of finding why this standard has been rated as “poor.” There also does not seem to be much consistency in terms of returning reports around and out. I’ve received a couple of emails, for instance, from [...] saying that they have not had a report from the inspector when the inspection was six weeks ago. They should in principle receive an inspection report in five working days. I don’t know what they’ve gathered centrally on consistency. But maybe that’s the kind of information QA managers, who are centrally-based, should be gathering and see what should be done and the best way to tackle the problems.

16: Inconsistencies primarily lie in inspection reports and final ratings, especially from region to region. As I mentioned before, this problem is amplified by the fact that the whole exercise is highly subjective.

17: No. Inspectors have done a great deal of what consistency means however they do not have an overall approach of quality insurance that monitors the consistency of those who do the quality insurance. So the four regional managers that do the quality insurance do not have many tools, or guidance, on how to grade the various reports. Inspectors do not get together very often or share feedback or compare to one another. Inspectors are not terribly aware on how well they are being consistent.

18: The inspections do help to drive improvement among pharmacies – as they do not want to be rated as poor. Good pharmacies will inspect their processes before an inspection and make changes to ensure they are providing a good service for customers. Other pharmacies will respond to the feedback they receive from the inspector about the quality of service they provide.

19: The consistency varies, as it is up to individual inspectors’ discretion how the inspection takes place and what the focus is

- How do pharmacies experience inspections (e.g. how do pharmacies prepare for inspection; is advance notification helpful)?

I1: The process I currently follow is sending a standard notification letter out to pharmacists (generated by the inspection database) and making them aware of an upcoming inspection. The letter states that the inspection will take place in the next six weeks, we don't provide a date. In my view, there isn't a lot of preparation that goes on prior to the inspection. If that was the case, we would be seeing more outcome-focused examples and pharmacists showing clear evidence of having met the standards. However, this is not what we see in practice which suggests to me that pharmacists don't really plan much ahead of the inspection.

I2: My process is: I introduce myself, explain the process of inspection and what happens after the inspection. And explain to the pharmacy it is their job to provide me with evidence. And that it is my job to document it. I then ask them to describe the pharmacy (in terms of location and services provided) and then I generally work through the standards in the order that they are published. I also usually check with the pharmacist that they are happy for me to wonder around during the inspection (it's a good practice). I also speak to the non-pharmacy staff (i.e. dispensing staff) about how they can feed back and whether they have concerns to raise. The inspections tend to take around 3 hours but I have had inspections which lasted 5 hours. 3 hours seems too much even if inspections take place every three years. This is because pharmacies are busy places and it feels intrusive and can be draining for both sides.

I3: I think generally the inspection is a positive experience based on the feedback I've received from the inspections I've carried out. There is a disappointment if they don't get good ratings or where they feel they had genuinely surpassed themselves when it comes to driving better patient outcomes. But I think they generally understand that the inspection report is not meant to name and shame but mainly to highlight areas where they can improve (including areas where they are doing well and ought to sustain improvement).

I4: It varies from pharmacy to pharmacy. We do both announced and unannounced inspections. With the announced, we usually send them a letter to inform them of our visit within six weeks of receiving the notification letter. With preparation, it depends again - some pharmacies would have done a lot of preparation in expectation of our visit; others would not have done anything. In terms of how pharmacies experience inspections, I would say that, based on my experience, initially pharmacists tend to be a bit wary. What I like to do is to break down the inspection to them and explain to them about the standards and what I'm going to do. As the inspection goes along and towards the end, they usually are quite happy with it and they say that they have a better understanding of why we do these sorts of inspections and they feel that they've learnt things that they had probably not picked up on before.

I5: On most occasions, they will be notified via a letter of an upcoming inspection. They will be informed within six weeks of the inspection. At the inspection, I normally check whether they understand the standards and have had a chance to read them. Then I will go around, check the premises, take notes and at the end of the inspection, provide the pharmacist with a summary of my key findings as well as any positive elements or actions they would need to take to improve. I will also let them know what the follow-up process will be. I have 3 days to

write the report of evidence. I then pass on the report to my line manager to review/QA. My line manager usually has two days for reviewing. We then send a draft report to the superintendent pharmacist. I get him/her to sign (electronically) just to confirm they were the responsible pharmacist on the day. They can also comment on the report and reply to us within five working days. If certain standards have not been met, then we would generate an action plan. This will be sent as a separate document, along with the draft report. The superintendent pharmacist is required to fill out the action plan to say what actions they will take and by when. Once we get confirmation that the draft report is okay (and if there is no action plan), then it's just a matter of saving and recording the date of the email response and emailing the final report. The inspection process would then be complete. If, on the other hand, there is an action plan, once this is sent back, we save it and make a note of when it needs to get completed by, generate the final report and then inspection process is complete once we get the final notification that all the actions have been completed. Duration depends on a case-by-case basis as some actions require more time.

16: The experience varies. Some pharmacy teams are more involved than others. In some pharmacies, the pharmacist will encourage the whole pharmacy team to engage while in others, this is regarded to be the pharmacist's responsibility.

Following notification of an upcoming inspection, there have been instances where pharmacists have contacted me to indicate their availability (i.e. date and time). Others do not really bother. Usually those who engage with me right from the start are those who are very positive about inspections and who want to show they are up to scratch. Consequently, the level of evidence and the extent to which pharmacists and their teams demonstrate how they adhere to the standards varies by pharmacy. Some pharmacy teams are very good at presenting/articulating evidence. Others are less able to do that or do not bother going that extra mile.

17: There is a 90 per cent approval rating. The inspection seems to be well received, there are some issue like the rating used but generally it has been well received. Regarding the notification in advance, some people would like an appointment but the majority realises and accepts that the 6-week window is probably a reasonable approach.

18: This has been the most noticeable change since the new standards and inspection process were introduced. Pharmacy inspections now take a lot longer and is more intrusive. They previously took on average 2 hours. Now, the inspection takes at least 3 hours and can take 5 hours if the pharmacists doesn't have the correct information or something doesn't work out as planned in the inspection. This makes it difficult for inspectors to complete more than one inspection per day. The pharmacists have to prepare for an inspection. They have to collect evidence that they are meeting certain standards and extract information from their systems. This information can be quite detailed, and is not always kept on the premises. Therefore pharmacists have to bring in additional information for the inspection. This can be difficult, particularly for smaller pharmacies as it takes quite a lot of time (and if they don't have any additional staff this can mean preparation in their own time). In general, it is easier for larger chains to prepare for the inspection, as they have more staff and staff that are designated to collecting the information for inspections (ensuring that all relevant information is available for a pharmacist prior to the inspection). As with all things, pharmacists have given a varying amount of time and effort to preparation – therefore there are some who are over prepared (have all the information required and additional information they have also

collected), whereas others may not have had the time to prepare adequately and don't have all the required information present when the inspector arrives. The inspectors give notice (a window) of when the inspection will take place. Some will tell the pharmacist exactly when they are coming, to ensure the relevant staff are at the premises and they have collected all the relevant information. This is because the inspection is easier if the correct staff are there (there are enough staff there for the pharmacy to continue functioning and the pharmacists with the correct information and knowledge is present). The inspection consists of the inspector examining the evidence that is provided by the pharmacist, observing what is happening in the premises while they are there (for example customer service), speaking to the pharmacist and staff at the premises and inspecting the premises to ensure it is a safe environment. However, the inspector's role is not to try to "catch out" the pharmacist. They see their role as supporting the pharmacist (as long as they aren't doing anything illegal), and pointing out where improvements could be made.

I9: The main issue that was raised here was the length of the inspection. The length of the inspection can be anywhere between three and seven hours per pharmacy. This means that pharmacies are required to run their business and respond to questions and provide evidence for up to an entire day. This is quite difficult for the pharmacist and the inspector. The same judgements are required for the GPhC inspections, which in his opinion shows the strain they are under. Due to the length of the inspection, it is unlikely that pharmacists will be able to visit pharmacies once every three years.

I10: The pharmacists experience the inspection in a slightly different way than previously, beyond the length. The new inspection focusses on risks and implementation of plans, therefore pharmacists need to provide evidence of these policies and explain how they are being implemented. This means that they have to prepare evidence to present to the inspector. The pharmacists do not have to be told when the inspection is taking place, but they are generally told the period over which an inspection will take place. However, the inspector will try to visit when the regular pharmacist is there, as it means the information they get from the inspection is better. Therefore, if a pharmacist contacts the inspector to say they will not be present on a certain day, the inspectors tend to arrange their visits around the pharmacists availability. The inspector will also tailor the approach of the inspection based on information about the pharmacy. Therefore each individual pharmacy might experience the inspection process in a slightly different way.

How helpful is the GPhC's inspection decision-making framework when thinking about inspections?

I1: I don't think it's particularly helpful. It's been redrafted twice in the last 12 and 18 months. I think it's a struggle for pharmacists to understand what it means. A lot of the examples in the "satisfactory" and "good" categories overlap a lot. Whether you're an inspector or a pharmacist, the framework leaves you a bit confused as to what the ratings will be. Will the evidence push the pharmacy towards a "good" or "satisfactory" rating? Also, a lot of the standards are too vague, preventing inspectors to measure consistently. So overall, the framework is an honourable attempt but I don't think it's helping that much nor is being used to the extent it was probably envisaged by the GPhC.

I2: It has some help but it needs to be treated with caution or it can turn into a checklist.

I3: I think it's reached a stage where it's not as helpful as it used to be in the beginning. Inspections have evolved and I don't think that the inspection decision-making framework has kept up with that. I find it too prescriptive.

I4: I don't use the framework during the inspections. I'm focused much more on collecting evidence during that time. I tend to consult the framework when I'm writing the inspection report. The framework is helpful when I'm trying to check for examples of when pharmacists would be rated "good" or "satisfactory" in relation to particular standards.

I5: The actual decision-making framework has not been the easiest document to work with. The problem is that it was developed before we were actually expecting the outcomes-focused standards. The way the framework was worded, it was difficult to match your evidence with what the framework was telling inspectors what they needed. However, I think we've learnt to be more pragmatic as the new inspection model has gone along, we've learnt to write better and clearer evidence allowing the reviewer to understand inspectors' judgments and ratings even if specific examples are not necessarily mentioned in the decision-making framework but are clear examples of good practice. I don't tend to refer to the decision-making framework as much as I used to. I think the more inspections we do and the more aware we are of what we need to capture to support our judgments, it's no longer as a bigger tool as it used to be. It's certainly something I always have at hand as it's a good reference but it is not key to the whole inspection process.

I7: The decision-making framework is not useful at all. It has contributed to the polarisation of most of the pharmacies being "satisfactory" and it does not explain everything. It talks about the difference between "satisfactory" and "good" but does not talk much about "poor" and "excellent" which are also rating that could be applied.

I8: It is fairly useful, but does still leave scoring open to interpretation which does mean inspectors discretion is important when the results (and report) of the inspection are finalised.

I10: A little but still discretion of inspectors.

Do inspections help pharmacies meet the standards more effectively?

I1: The feedback we receive from pharmacists after inspections tend to suggest that inspections help build the understanding around the standards and how to meet them. However, it is difficult to say whether pharmacies are able to meet the standards more effectively. Our model does not include going back to pharmacies that were rated "satisfactory". A majority of pharmacies are rated "satisfactory." From that point of view, we would not know how much of the advice shared as part of inspections has been taken on board for a majority of pharmacies. The next time we inspect these pharmacies will be in three years' time. But by that stage, we cannot substantially say that the last inspection has significantly impacted on the quality of the pharmacies. The only way we can measure whether inspections have led to an improvement in the quality services is where pharmacies have been rated "poor." They would have received an action-plan and we can measure improvement against the action-plan. That's the only scenario I can think of where we could clearly demonstrate that there have been improvements in the quality of pharmacies (initially

rated “poor”). However, in saying that, at the moment we are taking a very pragmatic view. Inspectors are not compelled to make a physical re-visit to pharmacies within weeks that they have been rated “poor.” We would ensure that they have been provided with an action plan and make a judgment about whether an actual physical re-visit is required. In any case, poorly-rated pharmacies are seldom. They constitute about 3-4 per cent of the thousands we inspect.

I2: Yes. I think when we go around the second time it will be even better because pharmacies would know how the standards are interpreted by us.

I3: Absolutely. Inspections definitely help improve understanding and awareness of the standards.

I4: Most definitely – I think they become more aware of why they are doing certain things and how they can improve what they are doing. It allows them to think of what they can do to ensure they meet the standards and provide the best possible service to their patients.

I5: Certainly, inspections these days not only ensure that standards are being complied with, but also, as inspectors, we are there representing the GPhC to ensure there is a good understanding of standards and pharmacists are engaged. The actual inspection is key and will continue to be key in ensuring good levels of practice are maintained.

I6: We try to help pharmacies as much as we can. But then it all depends on whether pharmacies are implementing the changes where needed or in the areas of most concern. As I was saying before, the problem is that we don't get to follow-up with pharmacies so it is difficult to say whether the standards are consistently being adhered to or improvements are being sustained.

I7: Yes, it makes a great contribution to that.

I8: Yes, as pharmacists fear a poor rating from an inspection, therefore they want to meet the standards. However, this was also the case under the previous system of regulation.

I10: Yes. Some pharmacies are very good, and always meet all of the standards and get very good scores. The inspection process has very little effect on these pharmacists. However, for the average pharmacist, the inspection will pick up some aspect where they can improve and meet the standards. Therefore it does help to meet the standards more effectively. I feel that examinations are very useful, like exams to assess students, otherwise it is difficult to know if they are following the standards.

Does the level of awareness of standards change as a result of inspection?

I7: The awareness changes but probably not the acceptance changes.

I8: The inspections do raise the level of awareness of the standards both before and after the inspection. Pharmacists use the standards before the inspection to prepare, and some pharmacists have their knowledge of standards raised during and after the inspection.

I9: The level of awareness does increase as a result of the inspection. This is both before and after the inspection. Before the inspection (once the pharmacist has received notice of the inspection) many pharmacist will look at the standards and see what is required, which raises their awareness of the standards. After the inspection, pharmacists are more aware of the standards and how the inspectors are implementing them. However, he does not feel this is a big issue due to compliance with previous standards.

Which elements of an inspection – involvement of the whole pharmacy team, facilitating learning and good practice, collecting and agreeing evidence – seem most important in supporting pharmacies to meet the standards and to improve?

I1: The best way to answer is to consider which standards are the most critical for engaging staff. There a few standards within principle 1 and most standards within principle 2 as well as standard 4.2 that relate to staffing issues and staff engagement. If staff can explain to me clearly about how they provide services in a fluent and confident manner, that would tend to give me confidence that services are being provided safely. At the end of the inspection, I'll point out areas where they've done well and/or less well. I try to get staff engaged so that they feel that they know it's not only about understanding the standards and delivering services safely but also contributing towards improving the safety as well as the quality of pharmacy services. I think that's what will influence ratings upwards.

I2: Involvement of the whole pharmacy team. The pharmacies that perform better are usually those that work as a team.

I3: All of them are really important. Based on feedback I receive from pharmacies, I think the learning experience, especially what they need to do to comply, is what they appreciate the most. And that, in itself, involves the whole pharmacy team. These discussions during inspections, when we are collecting the evidence, always involve the whole team. They give an opportunity to the whole pharmacy team to demonstrate how they meet the standards on a daily basis.

It seems that the inspections and the discussions we have with the pharmacy team have a knock-on effect on involvement of the team to drive better outcomes and sustaining improvement.

I4: I think it's getting the whole team's buy-in. I feel that if the inspector talks to the whole team and shares learning with them, the team can also understand why certain things are being expected of them to be done in a certain way and its' not just the pharmacist telling them to do because that's how they expect things to be done. When collating the evidence and at the end, when we feed back the evidence, I think that the wrap-up with the pharmacist helps them to understand and get a clearer picture of what they are doing well and where they may need to improve. I think engaging the whole team just makes staff more willing to make the changes and not feel like they are being told off.

I5: They are all important but personally, what I like about the new inspection process is that “whole team” approach. I’m always keen to speak to as many members of the pharmacy team as possible. I certainly think that this approach has improved awareness, understanding and engagement with everybody and their role in meeting the standards.

I6: It’s a difficult one to answer. It varies from pharmacy to pharmacy. There are teams that want to get involved in the process. Some pharmacy teams are very well briefed so that they can all chip in. But this is not the case with all pharmacies.

I7: The most important thing inspectors do is to challenge pharmacists’ understanding and the acceptance of what they do. By asking them to provide evidence, make them think about what they have to do.

I8: Observing in the pharmacy to see how things work is very useful, as the inspector can see if the processes which the pharmacist says are in place are actually being used, and how well they are working.

I10: A successful element of the inspection process is speaking to the staff working at the premises as well as the pharmacist themselves. This helps the inspector discover if the policies the pharmacist says are in place are actually implemented, and the inspector can gather evidence on how it is working.

What is the impact on pharmacies after inspection, particularly for those without action plans? Does it provide a continued focus for improvement?

I1: The difficulty is that most pharmacies are rated “satisfactory” and don’t get action plans. We don’t get to re-visit which makes it difficult to determine the extent of improvement quality and safety of services. Regarding pharmacies that do not receive action plans, we may suggest areas for improvement in the inspection report but we are specifically refrained from providing prescriptive guidance to professionals – it is not the role of the regulator to do that.

I2: Even without the action plans standards would have been driven up. For example, I share good practice from other pharmacies (obviously anonymously). But I think that often gives pharmacies something to think about – how they can develop their own services to the benefit of patients. In my opinion, most people are finding inspections to be a positive experience and they are finding ways of improving their services following inspections.

I3: I think so. Obviously if they are a good pharmacy, it is motivating and encouraging for them. They take pride in high ratings and would want to maintain these good ratings. For pharmacies with action plans, the vast majority is keen to improve.

I4: To be honest, if they haven’t had an action plan, I haven’t really had to go back so I cannot say that changes and improvement were continued. But what we’ve started doing recently is, even if they are meeting all the standards, give them ideas on how they can improve further. We often refer them to the decision-making framework so that they know what sorts of things we look for in good pharmacies. Through this, we hope they can build on what they are doing and aim to improve.

I5: The pharmacists often provide feedback on how inspections went. I've received emails from owners where they explain that they/their teams have found the whole inspection process supportive and very encouraging and that they would be taking all recommendations on board to improve even in cases where they were rated "good." I don't have any evidence whether that happened or not, but the fact that we have a couple of people saying that inspections triggered a pathway that they are going to follow continuously for making improvements is very encouraging! As regards pharmacies that have had action plans, so far, in most cases it's been very interesting to see that pharmacies have fully accepted their failings. A couple of pharmacies have also expressed how important inspections have been in making them more aware of the standards and the outcomes of the standard. With this better understanding of the standards, they're looking at improving not just meeting.

I7: They better understand the standards and what they could improve. When a pharmacy is under "satisfactory", inspectors will give them indication on how they could improve. In the inspector's judgment, they might think a pharmacy does not need an action plan because it's not a serious problem. For instance if the record keeping was not accurate, inspectors might make a comment like "the records should be completed more often", they will not provide details like "records x, y and z should be completed four times a day". Action plans are for more serious things.

I8: It can help with helping improvement, although it is too early to say. As inspections now take much longer, there is less time for an inspector to re-visit pharmacies to check on their progress and see how they are doing in between inspections. The inspection process can't really damage patient care.

I10: Limited. I feel that some pharmacists may look at their report and think how they might improve, but others could be disheartened that they were "only average". I feel that the pharmacists who would use the inspection as a means to improve (even though they don't have to) are the pharmacies which are very good already, and would be looking at ways to improve even in the absence of the inspection. For other pharmacies they will see the inspection report as evidence that what they do complies with the legislation and they can continue with their business without making any additional investment.

Are there any unintended positive/negative consequences of regulatory inspections?

I1: Overall, the approach is right in principle, especially about how we engage with pharmacies. It is far more relevant in comparison with what we used to have in the past. As a result, pharmacies find inspections more useful and it becomes more apparent to them what we are trying to address and what they should be doing to demonstrate compliance and being outcome-focused in their approach.

On the other hand, the number of standards is unwieldy and we don't need that many standards to determine whether a pharmacy is operating as it should. We could probably reduce the number quite easily without having the worry of missing something which might potentially be an area of significance to patients.

I2: Too much time spent on inspections, as mentioned above. On a more positive note, they have positive impact on pharmacy improvement.

I3: Some of the standards around staffing have had an effect on what is expected of pharmacists or pharmacy professional in terms of targets. This is what we've been told.

I4: No

I7: The only unintended consequence was that inspection takes longer and that the people are unhappy with the labels. They are unhappy with the labels because the distribution of pharmacies across the four rating does not seem to reflect the perception of the pharmacy.

3. Action planning

Is action planning an effective intervention leading to sustained improvement?

I1: I'm not sure it has been that effective. Action plans are reserved for pharmacies with poor ratings. On the other hand, some pharmacies may have obtained an overall "satisfactory" rating but they may not be meeting specific standards for which they can still receive an action plan. However, combining these two groups, it's not a massive number of pharmacies affected. Of 5,000 pharmacies we could be inspecting, about 500 could be receiving an action plan. Of these 500, the action plan could be relatively trivial and not require massive changes. So, in my view, action plans are not, in practice, a crucial tool for improvement.

I2: For most places it is but occasionally you will come across a pharmacy (often a single-occupied) where the pharmacist or owner does not engage (i.e. they do not comply with the action plan) and if this is the case they often will not engage even if we go back again and again. Pharmacies do not comply in a sense that it is difficult to make a contact with the owner, or sometimes language barrier is a problem, or they say they are going to comply but they do not do this because it requires staff hire for which they do not have budget.

I3: I have had a couple of actions plans where the results have been positive. Others thought they had implemented the required actions, but when examining the changes, it was revealed they had not really made the improvements required. This can prove quite time-consuming involving a lot of coercing and chasing-up.

I've also had a couple of other actions plans that were not met. That's difficult especially as to whether we should be taking any formal action. In general, I'd say that there's a range in terms of whether action plans help bring positive changes.

I4: Most definitely, especially amongst poorly-rated pharmacies. I think the action plan is very effective in helping them make the changes. In the past, I have inspected pharmacies that were not performing as they should. But upon re-visiting and following-up after they've had time to make changes in accordance with the action plan, the pharmacy is a totally different place. And we do get positive feedback from the pharmacist and the pharmacy team in relation to action-planning and how it's helped them improve.

I5: I think it's certainly helped pharmacies in terms of improving. The action plans focus the mind on the standards and the outcomes, leading to better working practices.

Whether this will be sustained or not, I go back to my comment regarding the different groups of pharmacies – there are groups who will sustain improvement and maintain quality and safety but unfortunately there will be a very small minority who may decide to meet the requirements of the action plan but will not see the bigger picture of the importance of maintaining that and are likely to slip back to an area of not meeting the standards. As an inspection team, we therefore have a duty to be aware of them and have them on our radar because we know from historical experiences they don't have that engagement to maintain.

I6: It's not easy to follow-up. The new model encourages us to verify remotely if changes have been made. We should be able to go back to a pharmacy if we have significant concerns about the pharmacy. At the moment we only get verbal assurance that things have been improved.

I7: Yes, but it's not perfect. Inspectors tend to be as specific because they are encouraging people to run their investments and make their own decisions. However, sometimes, action plans can be more explicit when asking people what to do.

I8: Again, it is difficult to say as not many action plans have been issued and it is unclear if any changes have been sustained due to the short time frame. It might help to focus some pharmacies attention on issues and lead to a sustained improvement, but with others they may change to satisfy the action plan then revert back to old ways of working. It will be difficult to know if changes have been sustained as inspectors have less time and freedom to do follow up visits in between inspections due to the longer nature of inspections.

I9: Depending on the pharmacist, the action plan can be useful. However, it is not clear to me what action would be taken if a pharmacist failed to comply with the action plan. The inspectors and GPhC can only bring a legal case against a pharmacist for fitness to practice, and failing to comply with an action plan does not influence fitness to practice. Therefore if the pharmacist sees this as something that they want to improve they will, but others won't.

I10: There is an issue around sustainability. Following the inspector issuing an action plan, they go back to pharmacy (if rated poor) shortly afterwards. But due to the time pressures mentioned earlier, unless there is a complaint they won't visit the pharmacy again for another 3 years at least. Therefore they don't know if the suggested changes have been sustained.

Where an action plan is needed, are the right areas being highlighted in inspection reports, to ensure a focus on improving quality, including safety?

I1: Within my reports, I always attempt to make clear where the areas of improvement are. I would assume other colleagues do the same. I think most inspectors seek to point pharmacists to the right direction, in terms of improvement, in action plans and inspection reports.

I2: Yes, they are. Usually the owners of pharmacies agree with us.

I3: I would think so. As far as I am concerned, I always try to make it clear to the pharmacy where the areas of improvement ought to be. To give you an example, I recently rated a

pharmacy “poor” for not meeting the requirements under Principle 3. The physical conditions of the premises were actually very poor. But because of that, it affected many other standards. And consequently, there were many other areas that required remedial action which I highlighted to the owner. That’s because I could see a genuine patient safety issue and explained to the owner why so many changes were required of him.

Common areas that are often lacking and which I’ve included in my inspection reports include: safe-guarding (although with growing awareness, this area has improved significantly as far as the pharmacies I’ve inspected are concerned); physical conditions of premises, in particular, cleanliness; compliance with legal requirements (e.g. good record-keeping; providing information to patients when labelling, etc.).

I4: I think the most common issues are around governance. For example, pharmacies’ Standard Operating Procedures (SOPs) may not all be fully in place or may be slightly outdated. Or SOPs may not have been read and signed by everybody, or pharmacies do not have effective procedures to deal with incidents and errors. Other areas I’ve come across and have highlighted in my inspection reports include: providing services such as Monitored Dosage Systems (MDS).

I5: I think it’s certainly helped pharmacies in terms of improving. The action plans focus the mind on the standards and the outcomes, leading to better working practices. Whether this will be sustained or not, I go back to my comment regarding the different groups of pharmacies – there are groups who will sustain improvement and maintain quality and safety but unfortunately there will be a very small minority who may decide to meet the requirements of the action plan but will not see the bigger picture of the importance of maintaining that and are likely to slip back to an area of not meeting the standards. As an inspection team, we therefore have a duty to be aware of them and have them on our radar because we know from historical experiences they don’t have that engagement to maintain.

I6: We have some metrics that help us determine when an action plan is required, or where we can be tolerant

I7: It’s surely highlighted enough and it is obvious to the one receiving it.

I8: Yes, I believe that the right areas are being highlighted to improve quality. It is bound to improve patient safety and outcomes.

I10: Yes, I feel that they are.

Does action-planning lead to greater accountability/ involvement from pharmacy owners and superintendent pharmacists?

I1: I think it depends of the structure of the organisation. In larger organisations, there could be quite a hierarchical structure – it could be that management drafts the action plan. In smaller organisations, this could fall back to the pharmacist and his/her team.

I2: Yes, I think it does. Particularly with larger organisations. Sometimes smaller pharmacies need to be reminded that accountability sits with the super-intendant but mostly it is not a problem. I am not aware of an action plan having a negative impact – it is only positive.

I have had a comment – this is regulation working well – and this is a comforting comment to hear. Nobody likes to be told they are doing a bad job. However, a recent comment I heard was that it was a really positive experience. We have not realised that there would be such a positive feeling amongst individuals.

I3: It varies. Although I tend to see action-planning delegated to the responsible pharmacist in many cases. There are however instances where the owner/superintendent pharmacist are keen to be involved, especially where the superintendent pharmacist is the regular pharmacist.

I4: Definitely – because I think the action plan highlights to them what's not working well. In many cases, pharmacy owners may not have involvement in the pharmacy so they may have procedures that they've passed on to the pharmacy manager but they may not have followed up to see if they are being carried out or not.

I5: Yes, because the report is written in such a way that, where needed, it is made quite clear that management procedures are not really up to scratch.

I7: Yes

I8: There is greater accountability from local area managers and pharmacy managers if an action plan is issued. It becomes clear that action is needed, and they have a specific time frame (10 or 20 days) to implement change. This does help to involve managers in the process of change.

I10: It depends. Some pharmacy owners and superintendents' delegate downwards, therefore the accountability falls on the branch manager or pharmacist. However, others will take responsibility for the action plan and ensure remedial action is taken. It is difficult as the regulations and business organisations do not specify who is to be held accountable for the action plan.

Are there any unintended positive/negative consequences associated with action planning?

I1: I would not say that there have been significant changes as yet. It seems that this message on being more outcome-focused is not being communicated enough or pharmacists are not picking up on that. If the standards were principally outcome-focused, we would have a lot more "good" ratings out there. Because, generally-speaking, "good" ratings are awarded if the pharmacy can provide compelling evidence that their service is highly outcome-focused and not merely safe for the patient.

I3: It is sometimes difficult to test whether the action has been met as we do not always follow-up with poorly-rated pharmacies. We are trying to raise standards through inspections and at the end of the day, those with action plans have a bit more to consider and yet we are not able to evidence that as well as we would like. I think that's an unintended consequence.

I4: I can't think of any.

I6: No, not that I can think of.

I7: Some of the action plan are quite poor because inspectors are not specific enough at the start.

4. Reporting and publication

Does the provision of inspection reports and ratings provide an incentive for continued focus on quality provision of pharmacy services and improvement?

I1: I don't think it does provide an incentive at the moment as we don't currently publish reports and ratings. At the moment, I don't think there are too many pharmacies out there who would have been inspected who have the enthusiasm to want to get higher ratings to show their pharmacy in the best light.

I2: I think so. And this is seen in bigger organisations mostly as smaller ones have not seen a report yet. The reports are probably too long just now – being 3,000 words. It is difficult – the public have a right to know to decide which pharmacy to pick up their prescriptions from. Public reporting is a good thing but it should be very succinct – the reports are too long and might prove too overwhelming for the customers. We should just summarise whether the pharmacies meet our standards or not.

I3: Most pharmacies are doing a good job, but only get a rating of "satisfactory", which is often very demotivating to them. I think the ratings do help raise the standards but we are in danger of demotivating if we don't have another look at the grading.

I4: I think most definitely, especially amongst poorly-rated pharmacies. I think nobody likes to be rated "poor." And when this actually happens, it's like a real wake-up call. It prompts them to put things right so that they can come higher up on the rating scale. For example, there was one pharmacy that I had to go back to a number of times as they were quite slow in completing their action plan. When I had first visited the pharmacy, it was very untidy, very cluttered and did not have any dispensing system in place. They were supplying blister packs to a large number of patients and the way the service was being operated was very unsafe. They had a lot of outdated medication on their shelves. But over the course of the visits, they improved massively by de-cluttering, getting rid of expired medication, tidying up their shelves and reducing their stocks. They completely turned around their MDS process which is now provided in a much safer manner. What was even more positive, of the two times I was there, there were two different locum pharmacists and both of them commented on how safe they felt working there.

15: Ratings are controversial, but I think it's more the wording of the ratings. For example, "satisfactory" has a negative connotation in many people's minds even though it means they have met the necessary standards or requirements. But having ratings is important as it does push improvement. It encourages pharmacies to give their best and improve and sustain that level.

16: *The interviewee chose to provide a general response on reporting.* I think that if you publish ratings, the public is very much influenced by such ratings. This can have two potential impacts: (1) pharmacists may start challenging the ratings; (2) pharmacists will use these ratings as a basis for improving. I'm inclined to say that the former is more likely to take precedence.

If we go ahead with publishing reports, we will have to ensure that commercially-sensitive information is not divulged.

17: It does for a period of time but then it is less pressure to drive people towards improvements. Once a pharmacy gets the inspection and the action plan, they are much focused. But experience suggests that after 18 months to two years, people seem to be less aware than they were.

18: The inspection reports need to (and do) highlight what has worked well as well as areas that need to be improved. This will help focus pharmacists on what they are doing well and need to continue doing as well as highlighting areas where improvement is needed.

19: This is debatable. The reports are subject inspector discretion. Instead of pharmacists thinking "how can I improve to become good" they might look at the scoring and think "how did pharmacy X get a good and we got average – we do x, y and z exactly the same as them, but for y they got good and we got average." It depends on inspector discretion as there are no statistics to be assessed. Will the scoring system stand up to scrutiny of publication? It might bring more conflict than driving up standards.

Feedback concerning the proposal to publish inspection reports and ratings

11: I think pharmacies are generally receptive to the proposal of having inspection reports and ratings published. I think the discussion enthuses them and I suppose, they may become more engaged when ratings are made public. I think it's the right step forward.

12: The reports should be shorter – we don't need to go to great lengths for some standards, i.e. some standards could be joined together (around governance and staff for instance – the ones that overlap). The four labels that we currently have are too complex – we should just have whether we meet the standards or not. Suggest removal of all labels. But we are now too far into the approach to do that.

I3: I often wonder what form the report would take as a lot of information in the inspection reports is commercially-sensitive. Also, the inspection report is lengthy and therefore, in my view, not punchier enough for members of the public to consult and understand what the relevance the report is to the final rating given to a particular pharmacy. If it's going to be read by the public, it needs to be clear and straightforward. At the moment, I think it's more aimed at the professionals themselves. The fact that a rating will "stay" with the pharmacy for three years, that could be difficult for them. There could be changes over time (e.g. ownership) and if they improve, that cannot be reflected in the rating. My concern is whether we are being fair with them at all times – the rating will no doubt encourage pharmacies to do their utmost best when they know their rating is going to be published.

I4: I think it will be quite positive. It will ensure that pharmacists and their teams work in accordance with the standards and achieve a safer service for their patients.

I5: I think we have to go ahead with the proposal. We now live in an age where every member of the public who uses a service has access to what other people thought about the service. I think it is key as it does help form your judgment of whether to use a particular service. I think we should not shy away from that. It's something we have to do. However, we need to agree on what we publish. I would be concerned about whole reports being published. For example, we have security arrangements explained in those reports and this is very sensitive information. So maybe a summary report along with the rating could be published.

I7: People are very anxious about publishing reports even though it would be better to have them published. First, it informs public as to relative manners of different pharmacies – people are able to move from one pharmacy to another if they are unhappy. Therefore, one of the unintended consequence of the publication might be that people move to what they consider to be a better pharmacy with better reports. However, consistency amongst report has to be of a high level. Second benefit would be that it puts pressure on people not to have a poor result and to quickly correct that poor result.

I8: This is a difficult area. I am not sure if the results should be published, or what form they could be published in. I do have concerns around consistency, despite the decision-making framework. This is because the ratings still come down to the inspectors' discretion. If this is then published and has a direct impact on a pharmacies business, it opens up to question, "Why is this pharmacy rated satisfactory where another with the same approaches in place is rated poor by another inspector?" This might make inspectors fearful of rating something as poor in case they get challenged, even if they think it is poor. There is also an issue around understanding. Will the public have enough understanding of the role of a pharmacist and how they work to understand the inspection report? If not they might pick up on the wrong themes. However, just publishing the headline rating (Good, satisfactory, poor) might not provide enough information for decisions to be made. This is a complicated area and needs to be fully considered before deciding whether and what is to be published.

I10: The model of publication needs to be perfect before any publication. As little as possible subjective judgements should be included. Maybe the number of reported mistakes by the pharmacy? However, some of the information which it might be interesting to publish could

be commercially sensitive and pharmacists won't release it. I feel there are better ways of driving improvement than publishing the reports.

5. Other

Any other points the interviewee wants to make, including potential areas for improvement.

I3: I feel that, at the moment, the focus is on conducting routine inspections which is fine. However, there are occasions where I feel inspections should be more targeted because there are very clear areas that require improvement. These targeted inspections could take place as a result of some information or intelligence we've received or previous inspections/investigations we've carried out. It would be good to have a model that can be easily adapted and allows us to target the areas of greatest concern and provide an in-depth inspection approach to that to help the pharmacist to meet the standards and introduce good practice. For the sake of consistency, it would be good to have more uniformity in the way we consider things – e.g. how important is record-keeping, how important is it to have information leaflets in medication boxes, etc. In our reporting, the language we use, the amount of detail we provide should be more consistent. Also, are we all clear about our understanding of the law? We need to be comfortable with what is acceptable and what is not. We should all be on the same page.

I5: I'm positive about the standards and the way they are inspected. It's had a huge impact on inspectors' workload. Reports need to be a lot more detailed. But, hopefully, the changes are coming through at pharmacy-level and will be sustained in the future. We should continue to work on improving the delivery of pharmacy services by using the standards and everything that's linked to them. I think we are moving in the right direction.

I6: I think the new model has dramatically reduced the frequency of inspections. Before the roll-out of the new model, I used to visit pharmacies on more regularly. My approach was to undertake "thematic" inspections – i.e. target certain pharmacies with serious compliance issues. If I visited a pharmacy and there was an action plan to be implemented, I would follow-up within a year or so to check progress. But now, with the new model, I cannot really "target" my inspections. I have to visit pharmacies within three years. Previously, under the old approach, I was getting out to do 20 visits on average in a month. But now, this has been reduced to about 12 visits per month. The new approach is creating too much inertia – we ought to be only content with verbal assurance from pharmacies that changes are being made and improvements are underway. We could probably try to adopt a more targeted or risk-based approach to regulating community pharmacies. Frequent follow-ups will not necessarily "over-burden" us with administration if inspections target specific areas of community pharmacy practice or high-risk pharmacies. With the new model, we are also encouraged to spend more time on the premises which may not be suited to the pharmacist or their teams, especially on very busy days. We could probably seek to streamline the inspection process. Maybe we could base our assessment on overall compliance with the general principles as opposed to each individual standard. As regards action plans, the initial thought was that follow-ups would be embedded in the inspection process. However, it seems that this idea has been parked for the moment. So what is the point of an action plan

if you cannot follow up? We cannot always be sure that appropriate changes are being made. As a member of the public, I would not be reassured. Sometimes pharmacies cannot provide evidence of change or improvement remotely.

17: Overall, something that is better than the decision-making framework is needed and action plans need to be more specific. Also more thought should be given to what they intend to publish because some ratings are going to be inappropriate for publication, and they need to think of that sooner rather than later.

19: The standards and inspection process do not allow inspectors to separate between issues surrounding the premises and issues surrounding the individual well enough. For example, the pharmacist might be outstanding but the premises poor – the report provides a single score for this. The inspections are taking too long at the moment which makes it very difficult for inspectors. It is hoped this round of inspection visits (the first inspections under the new system) will be used to set a baseline measure for each pharmacy, and after this inspections will focus on specific themes of the regulation to reduce the duration of inspections. Shorter and more frequent inspections are better than a longer inspection less frequently.

110: A significant problem with the inspection process is that inspectors are not allowed to give any advice on how to improve their provision. They can only judge. I feel that the inspectors need to be proactive on this front in order to improve service. This is because I don't feel that the professional bodies will fill the knowledge gap.

Annex 7 Notes of depth interviews with community pharmacy professionals

1. General views on inspections – THOSE NOT YET INSPECTED UNDER THE NEW APPROACH

How do you normally prepare for inspections conducted by the GPhC?

Pharmacists 1 (P1): Apart from checking that I've got everything up to date, I don't really. I do not do anything special.

P2: I do a self-assessment and some mock inspection.

P5: I have done quite a lot of preparation for it. Someone provided a folder, I have been through all of that to identify the things that need to be added in the pharmacy itself.

P7: In the old approach inspectors would just appear, for this new approach I have tried to do reading around, to find out what is going to be expected because obviously I do not want to get a poor report or satisfactory. I do not know what is required because there is not enough information. My thinking is there is not enough proper guidance, although they talk about what is required but not the specific things they are looking for. There is not enough help for independent pharmacies and we do become isolated, we work within our own, whereas multiple pharmacies got people working specifically on some aspect of the business.

P9: In terms of preparation, there are a certain number of things we do anyway that comply with guidelines. We also make sure that the staff are aware of what is involved and the processes that have to be undertaken when the inspector is here.

P10: In the past, we've never had to prepare. And it was always like that as inspectors want to know what's happening at a specific point in time as opposed to having us ticking all the boxes five minutes before having an inspection.

P11: I didn't find that much difference, to be honest. I have been to the meetings with regards to staff being asked more questions. I still did not feel the staff was asked that many questions. I agree in principle with the theory behind checking with staff but I didn't feel they were asked so many questions other than what they are used to.

P17: The general idea with [...], from our superintendent, is that we have a monthly checklist which we have to go through and we have to sign off a summary sheet every month. Our superintendent expects us to be inspection-ready at all times. So preparation for inspection is just a case of going through our checklist, which I think has been taken from the GPhC's guidelines, and make sure that everything is compliant.

P19: Nothing as such, this is what you do every day. You can't prepare for an inspection because if you are just carrying out the activities for one week to impress the inspector it's not fair on the patient, you have to carry on the activities every day.

P20: I think it's the case of taking information from the letter that we received and looking at the contractual guidelines and making sure we are adherent where we need to be. I think there is a lot more required with the current, new inspections. The old ones were a bit more hazard, in a sense that you knew the inspector was coming and we need to be prepared for it. But now it looks a bit more structured and need to make sure that we have got the right documentation in place. There is so much paperwork now that it's just making sure we got everything in files and are ready to receive the inspector. I literally have to take a day off just to make sure everything is in place. There is cost associated with that.

Approximately how much does your business spend as a result of inspections (excluding meeting an action plan if required)? Can you estimate roughly how much time your staff spent dealing with your most recent inspection?

P1: I cannot say. I did not devote a lot of time in the past, I just make sure that everything is in order. And then keep on top until the visit.

P2: Couple of days and probably it takes more time than for multiple chain pharmacies.

P5: Quite a lot. With the Standard Operating Procedures (SOPs) that I have to write up every of year. I might be spending a couple of days here and there whenever it's required. I guess it would take three working days.

P7: We have been following the standard operating procedure for a few years now, so my staff pretty much know what is expected of them and the procedures; especially on handling prescription, what we have to do with the procedure on waste, the deliveries. I expect them to read the standard operating procedure every year. On my own back I have prepared some questions to see if they understand what is expected. But I am going to do it more because we do not know what the inspectors are expecting from us. Just reading around, magazines, journals, what sort of things people have been asked. I try to get prepared. They do that all the time, I cannot give you a specific time.

P9: We have not had an inspection yet, but we looked at what the inspection process involved, which is very time-consuming and we try to make sure that we have well understood what the processes are. When we have an inspection, it should not be too traumatic.

P10: No costs involved. We haven't had any new inspections – from what I hear this will involve a certain amount of our staff's time. In the past, our staff was not involved at all.

P11: I did spend quite a lot of time on different quizzes and questions, I did ask the staff some questions, but as I said, I would have expected more questions from the staff regarding key aspects of their roles.

P17: About 20 minutes to half an hour. There are no other costs as far as I can tell. I think the premises standards are up to scratch. We comply with everything that is requested as far as premises are concerned.

P19: I practice by the standard every day, I do not look at the inspection as something I need to work on. When it comes to a habit, then when an inspection happens everything is still fine, you do not start shaking.

P20: It is easily a couple of hours. The thing is, I need to have double cover, because we are such a busy pharmacy. So I need to have a locum available when the inspector is due. So if the inspector decides not to turn up for any reason, that is an associated cost that has been wasted. Well, it has not happened yet, but what I wanted to say is that if the inspector were not to turn up, we lose out by having a locum. You can't cancel a locum at short notice. So, we would have to incur the agency fee as well as locum fee. So it is a real difficult constraint on us.

If you were to assess GPhC inspections against other inspections you've experienced from other regulatory bodies, would you say that GPhC inspections place a higher or lower burden on time and financial resources? Or are they about the same?

P1: Yes, it does place a higher burden just because we know it's coming. Trading standards, health and safety terms without warning. Apart from doing an overall procedure to make sure everything is in place, you cannot prepare specifically for those visits.

P2: Yes, much more of a burden.

P5: I would say it probably has, although the regular PCPs use to take quite a bit of time to get together as well.

P7: It has caused a massive burden and a lot of stress. Because it is always in the back on my mind, I do not know when they will be inspecting me. Obviously I am concerned about that. I have been reading in journals on what others are doing and the reports that have been written are not good. This is worrying. I think although I agree with inspection but they have to live in a real world. It is different if you work in a pharmacy or somebody just comes in for a couple of hours and inspect somebody. What is more important is the service that you are providing, the doctors around saying that you are providing a good service, that is more important rather than what the GPhC is expecting.

P10: I have no idea – I have never been inspected by another body.

P11: No, the time was about right. We usually expect a few hours as there's quite a lot to get through.

P17: I'd say the GPhC inspection places a higher burden, because of the time taken every month to be sure that everything is recorded as it should be.

P19: Time is the biggest burden. They are here for quite some time and it would be easier if they could come and work alone.

P20: Oh no, we take much more precedence over the GPhC because obviously it is the regulatory body looking after our profession. However, when we have the CCG inspection that is also not taken lightly because they honour us with their NHS contract. I would say they are on par with the CCG inspection.

How far would you say that inspections provide a continued focus for improvement? Can you provide some examples?

P1: The new guidance has provided a focus for improvement, yes.

P2: Yes, it makes us assess where we are in the context of standard. Help us to improve where we need to excel.

P5: Yes and no. A lot of this is to do with paper work, when a crisis happens the last thing you would be doing is writing your SOP before you deal with it and then you do your SOPs for another time. A lot of this is learning as you go along as well, things that happen to you or other people, can give you some other ideas on how to do things.

P7: I do not understand how they can judge in a few hour the performance of a pharmacy. I think that is awful and they are not helping us. They are actually judging us, the way a pharmacy is performing just in a couple of hours, it is not right.

P9: We are in the process of providing the best service we can to our patient. We are aware of providing service taking safety into account, carrying out the check and balances in order to provide a very good service. We all go to work with that in mind. The inspection process is too heavy handed and should be more of a supportive process rather than a penalising process. On a day to day basis we do the best we can, we know this because we have to complete a patient satisfaction survey each year. Our results show that we are providing a very good service. Our service is patient focused and not process lead. We customise our services around that.

P10: Inspections are about protecting patient safety and finding evidence we are doing that. I think inspections will continue to do that. We have not had any advice from inspectors in the past as there were no issues raised. Under the new inspection process, we know what's coming, so we are recording an awful lot more. In the past, verbal proof was enough, now it has to be written and proven. That's the difference!

P11: It's a good benchmark, even though we do audits and in-house practices and we have to review our standard operating procedures every two years, we constantly try to keep up and be up to date, we try to improve the way that we handle our workload and deal with our customers. But sometimes it is nice to have a fresh perspective and a little bit of a

benchmark. We can pick up on things we can improve so it is definitely a worthwhile tool. We do take it very seriously.

P17: I think it makes us keep on the lookout for all that could indicate improvement. We can highlight any mistake or problem and then do something about it.

P19: This would be more working examples. If an inspector sees something being done at another pharmacy and is being in an efficient way, they should share that knowledge. That would help our organisation as well. If you implement something that has been tried and tested somewhere else, it makes it much easier, and saves you some time, to fine tune a process already there.

Do you think there are any other benefits to your business from undergoing inspections?

P1: Under the current inspection no, because for the vast majority of it, all we can expect is satisfactory as the best. That's hardly something to be proud about.

P2: It helps to congratulate our team that are doing well. Motivation of the staff

P5: I do not know whether we think it's a great benefits or not. We have to do for example customer survey every year and that's not going to change. Things like that we have to do anyway. Once we will have to inspection maybe I will be able to say whether it is better or worse.

P9: I do not know what the benefits are but the benefits may be, if we had a particular question that needs clarification, the inspector should be able to give that information for us. But on a day to day basis our work involves around customer services.

P10: More clarity, as I explained before.

P11: Obviously, we have to stay in line with the GPhC standards. When the inspectors come around, sometimes they may have seen good practice in other pharmacies and they give advice to us regarding some of the pharmacies that graded well. Vice versa, if they see something that we're doing well, maybe they can cascade it around. That is beneficial for everybody.

P17: Mainly it keeps us on our toes. Meaning that we don't relax. We all comply with the standards.

P19: It allows us to measure ourselves, target for my organisation, this is where I need to be. The inspection allows me to measure the level of compliance and where there is scope for improvement or not.

What more could be done to improve the value of inspections and drive higher standards in patient care?

P1: I think the categories they are putting us into are not regarded by outside bodies, even though some shops are performing well. I was at a meeting with the inspector, and she said that no pharmacy had been rewarded excellent. I simply do not believe that there are no excellent pharmacies in this area. There are a lot of people doing very hard work in pharmacy, who are dedicated. If you cannot expect more than just a satisfactory, when you go to the health authority and say “I want to do this” they say “you are only satisfactory, you are not very good”. Our system is viewed by external bodies that are not being supportive.

P2: More transparency of the inspection. What criteria are going to be inspected? How do they make their judgement?

P5: I will be able to tell you more when I have it.

P7: Now we are going to be judged on whether it's going to be poor, satisfactory, good report. From all the reports only one pharmacy in the all country have had excellent; what are they looking for? They have to look at each pharmacy and see what they are good at, surely they cannot judge that. If I have a poor report, how is that going to reflect on everyone, on me, on my staff? I do not think it's achieving anything. Premises inspections that's fine. If they want to see how the quality of your work is, I do not think they can come for two hours and assess somebody's quality of work. The quality should be assessed by the patients' feedback, GP's feedback, other professional saying that's a good pharmacy or not.

P9: We work in a very dynamic environment, we are always working on the go. We do not have time to seat down and prepare what we will be doing in an office environment. We are working with the public all the time. If there are any particular issues that are identified during the course of that work then we can look at it and decide next time we will do it in a different way. It's a continuous process of improvement.

P11: I agree with the new format, I still believe that more questions could be asked of the staff. I found that still a lot of the inspection was taken up with the pharmacists; more questions could be asked of the staff so that they can provide the inspector with answers to their questions to really show that they are on top of their game.

P17: Not that I can think of.

P19: I think the inspector should come from the same background to better understand what they should look for.

2. General views on inspections – THOSE NOT YET INSPECTED UNDER THE NEW APPROACH

How did you prepare for your most recent inspection?

P3: I downloaded the guidance from the [...] website about the five different principles.

P4: No, we need to ask, when you go into a pharmacy, the staff if there has been an inspection, how did it go. Usually, there is an appointment for the inspection when the pharmacy manager is there, I am [...]. This is the manager that goes through all the process. I have only a general idea of what they will be asked for.

P6: I have been in the profession for [...] years so I always try to set good standard even before the new requirements came into play. Nine years ago inspectors came from the EU, they were brought down to show the UK model pharmacy. So you see we always try to improve our standard. Because we are right in [...], it is in our interest to make sure that we represent very good professionalism.

P8: I read over guidance and the different regulatory bodies in [...] and also from people who gathered some information on how to prepare inspections. I read through them all.

P12: To be honest, we have got a pharmacist here who took care of it. When we came to know that GPhC was going to conduct the inspection, she prepared a set of questions that they could ask. She made quite a big pile of questions and then she went through all of them with us - working expenditure, care home expenditure, medicine etc.— so we were briefed about what to expect from the inspection.

P13: The last inspection we had did not involve a lot of preparation time. As it has always been the case, the inspector sent us a copy detailing the things they would be checking on the day of the inspection. This is really helpful to us as it allows us to check that everything is in order, maybe the little things we would not normally check on a daily basis. To be honest, there weren't any significant differences between the old and the new approach – it was pretty much business as usual to me. Although I need to add that we got a different inspector and she was, by far, the best inspector we've had in a long time. She was very professional and definitely not judgmental – if something was wrong she raised it with us and helped us identify ways to resolve it. A few years ago, things were different. You generally felt that inspectors were equivalent to the police, always trying to pick on fault rather than helping us rectify any failings.

P14: The thing is that I wasn't actually present on the day of the inspection. (a) I wasn't told when it would take place; and (b) I was on holiday.

P15: Well, I did not really have time to prepare for the inspection. I did not receive any notification. The inspector just turned up on the day.

P16: Basically, we looked at the standards that were published by the GPhC and we analysed where we were against each of the standards. Then we made sure that everybody understood what each standard meant, so that if they were asked something about standards, they could talk about it. But we did not actually say to people: "if they ask you this question, this is the answer you're going to give them." What we did was more like: "This is what the standard means. Have a think about what we do that is connected to that. Then, if you're asked the question, you've got something in your head that you've already thought about that matches the standard." So it was sort of coaching but not scripting. We were encouraging people to be prepared, but without actually writing the script for them to repeat.

Were there any costs involved in preparing for inspections (excluding having to meet an action plan if relevant)? Can you quantify them? Were they significantly different from those incurred during past inspections?

P3: Just my time, which I suppose is costly.

P4: I have no idea about the cost

P6: We have not. In fact, a company phoned us up and it was all about preparing pharmacies to GPhC standards. They did approach us explaining the role that they play and how they can help pharmacy to achieve the GPhC standards.

P12: There was no cost involved because she made the questions herself and she briefed us, so it's part of our work as well. The briefing was about half an hour to 45 minutes, but she must have put in quite a lot of time of her own – she is one of our senior pharmacists here, so I'm not sure how much time she needed to make that questionnaire. In our day to day office we were made aware of things we should be paying more attention to if the inspection happens again. Everyone is being briefed about it and the new trainees and new employees are being told about this as well.

P13: None, as far as I am concerned. When inspections are due to take place, my pharmacy technician would be helping me out and we can get things done pretty fast.

P14: No. And I don't understand why you would need to spend any money other than if there was a complaint about shortcomings and we were required to take remedial work.

P15: There were no costs involved.

P16: No, no costs at all.

P18: No, there were no costs involved. And I don't think there should be any if you're doing your job properly. There are costs involved only where you are required to take remedial action.

You mentioned that you've spent about [...] of your staff's time dealing with your most recent inspection. Is that correct? Would you say that this is roughly the same time you've always spent on inspections? Would you say the new approach constitutes a greater or a lesser time burden than the previous approach? Why?

P3: Oh no, I spent maybe 2-3 months with bits and pieces and try to achieve those things. And it represents much more time compared to the other inspection. It's definitively a greater time burden because pharmacists not necessarily know what was expecting. Also the level of expectation was greater and because it's new, it's difficult to know.

P4: If everything is in order, it's easy to be prepared. It depends on how much the pharmacy needs to catch up, to be successful during the inspection.

Since I was not here during the inspection I cannot tell how much time they spent there.

P6: There is so much information and every day there are new information on the GPhC website. As much as we can, we do it as part of our everyday job, we try to keep in touch with the primary requirement and we try to make changes according to those requirements. In order to meet to requirement of the GPhC, I had to employ additional professionals to work with me so that the responsible pharmacist can try to delegate duties. But it is difficult to delegate once you have a business model in your pharmacy which is working perfectly, because someone is trained differently than the standards you are used to work with. Sometimes they do not know why they are following instructions, so it's a constant teaching process.

P8: It took me maybe up to five days to get where I wanted to be. I have not done any inspections before, so I cannot tell

P12: In a way it's a good practice, everybody is being briefed now and then so it's not separate from their work, it's part of their work. I appreciate it like that because it's learning by doing. It's more memorable than anybody giving you questions and you just "mug it up". To me, personally, it's a better approach, you're being briefed every now and then.

P13: I think the new inspection took slightly longer. It did not really impose a burden on us. The inspector was actually keen to gather as much evidence as she could but at the same time, it was a busy day. But she was very understanding.

P14: To be honest, it's minimal. If you are up-to-date with everything, then there is no significant amount of time involved in preparing for inspections. We should be ready anyway. I do not foresee any significant differences in the amount of time involved under the old approach and the new approach, not unless we do not know where the paperwork is or there has been a change in management.

P15: This time it was longer. In the past, inspections were much more focused on dispensing and pharmacy practice, while with the new approach the premises were also inspected. So, overall, it was longer than usual.

P16: Yes, I said in the survey "up to a month to prepare". We had the letter to say that we were having an inspection in the middle of [...] but we didn't actually get the inspection until the end of [...]. We had lots of time to talk and think about it and to prepare. We spent the first two to three weeks really concentrating to make sure that we were ready by the time the inspector came back to us. Then, it was sort of a constant refresher thing over the next six weeks until the inspector actually came. I'd definitely say we spent more time preparing for this inspection than for others because it was completely different from what we had done before. The last time we had an inspection was about four years ago and it was the same lady who did it. For the previous inspection, she came in and just followed the questions for which she needed almost "yes" and "no" answers. On the contrary, this inspection was

much more open-questioning and, rather than looking for a specific answer to a specific question, it was looking for a discussion about approaches to things and work practices.

P18: Yes, typically, we spend between 3 and 4 hours, although a few peers have told me they have spent about 7 hours. Inspections under the new approach take longer. From what I hear and from what I've experienced myself, inspectors seek to write the whole report during the inspection. The real aim is for them to gather the evidence but probably to avoid bringing work home, they do this in the pharmacy itself.

If you were to assess GPhC inspections against other inspections you've experienced from other regulatory bodies, would you say that GPhC inspections place a higher or lower burden on time and financial resources? Or are they all about the same?

P3: Yes, the level of expectation as in not achieving the satisfactory result could mean that you could move out from the register. The implication of the result has more powers and impact.

P4: For the inspection I cannot tell. It will depend on the pharmacy or the pharmacy manager and how well prepared the staff are.

P6: The pharmacy teams are afraid of the GPhC, some are not sometimes sympathetic and being helpful. This is a drawback, if I am not doing something right I would like to be shown how I could do better. It used to play a higher burden but a few months ago the GPhC came up with an understanding approach with people feeling a bit easy. GPhC realised it was a bit strict, they have changed their approach and attitude and we find it quite beneficial.

P8: Because it's public health focus, you just have to it.

P12: I have been working here for [...] years now so I do remember people earlier – I am not sure whether they were coming from GPhC but it's good in a way. It's not very similar to each other, they keep asking something different and more up-to-date kind of things, so to me it's not similar every time.

P13: That's quite tricky but I would say that GPhC inspections take slightly less time than others, especially when we get audited by [...] which I personally feel is a total waste of time as no one really benefits from them.

P14: No, not really. I don't think it places any burden on internal resources. We already do what is required.

P15: No, we mostly only have our own internal inspections.

P16: The GPhC's new inspection places a significantly higher burden than other regulatory bodies. There is a significantly larger commitment in terms of time opposed to the old style inspection and opposed to any of the other inspections we can get. But I don't think it's necessarily a bad thing.

P18: I think GPhC inspections definitely place a higher burden, at least for the time being. I think some of it is due to evolution and building confidence in carrying out these visits. I think there is a confidence issue associated with the new approach - inspectors are taking more time on-site. Maybe when they will get it right, the burden will be lower on pharmacists and their teams.

There are specific aspects of inspections you cited as important or very important in helping you meet the GPhC standards and improve (e.g. involving the whole pharmacy team, being able to demonstrate how standards are being met, the inspector signposting good practice, evidence being gathered, a report which records the evidence, feedback from the inspector).

Could you explain how these aspects of the inspection matter to you, your staff and the pharmacy in general?

P3: There were feedback but the majority was positive.

P8: I do not think they are important because I think the standards are a bit onerous. But having gone through them all, I was really surprised that the gaps that my staff did have, that I did not think we had. So in a way it was beneficial because I always have my staff with me, I have very bad in delegating. It was good but very time consuming and the evidence gathering quite onerous.

P12: Our pharmacist briefed us regarding the new laws, new paperwork involved or other things such as prescriptions which are not in line with the law so we need to liaise with the GP to get it changed etc. Because the GPhC is coming to inspect, I think we are doing more than what we are expected to do.

P13: I think the most important aspect of the inspection is the involvement of the whole pharmacy team. Staff feel they are part of the process and feel they are contributing to painting the pharmacy in a good light. With the new inspections, staff definitely have a much greater role to play than 10 years ago.

P15: We have weekly inspections in [...]. These are usually carried out by me. We inspect on all the different aspects that would have been inspected by the GPhC inspector. We also have monthly inspections from the area manager and longer inspections 3-4 times a year. All our inspections are in line with the GPhC inspections. They abide by the GPhC standards. Following monthly inspections, we may get (internal) action plans from the area manager if needed which we need to meet.

So for me, the GPhC inspection does not really add much. Our own inspections go beyond GPhC inspections. For example, the GPhC requires that we complete 5 CPDs a month. Internally, we have to do 12 a month!

P16: For us, the issue was (particularly for me) not to be involved. We were making sure that everybody (all the team members: the dispensary staff, the checking technicians etc.) knew what was going to happen. For example, if someone comes in and we are worried about their safety at home: everybody knows the safeguarding policy so they know what to do. So, on the inspection day, it wasn't me who was answering questions; it was the dispensers and

the ACTs. This way, we could demonstrate that everybody understood what policies and things were about and knew how to refer people to other relevant facilities.

How far would you say that inspections provide a continued focus for improvement? Can you provide some examples?

P3: Yes, I think so, we can focus on what is believed to be the most important to choose. It has given us a focus. We did not seem to have any gaps that we were missing in terms of paperwork. I did work for some time on gathering information that was in my view being relevant for the upcoming inspection.

P4: Yes, but if you have a member of staff with a lack of experience or who has just started, this issue will remain. It takes a lot of time to replace a staff with a suitable candidate.

P6: Yes, definitely. When I look back I can see how the practices of pharmacies have changed, the way they are laid out, how certificate are laid out, the way public has confidence in the qualification of people working there. All that has changed tremendously

P8: Yes, the things that he said – there was not really much – gave me a bit of understanding. To be fair we got a very rating which is rare

P12: Yes. We have new trainees and it's good in a way that they keep learning more things because of the inspection. Sometime they will not know what the inspector is talking about. But if they listen to it then it will be new information for them.

P13: I would hope so. It seems the culture is changing and inspectors want to help us in meeting the standards. If we continue to work hand in hand, we would be able to improve and sustain this improvement.

P14: We constantly have clinical audits anyway that are instituted. But if there were no inspection requirements, it might mean that our company would then place less importance on the clinical audits and the professional standards. So I feel that inspections keep the pressure on the commercial side of the business to maintain a professional environment.

P15: Not really.

P16: I think most pharmacies do not need that. I don't think we need somebody forcing us to be focused on continuing improvement. This is what we do in the standard way, it's not unusual

P18: It is something we ought to aspire to. As far as my pharmacy is concerned, we seek to improve on a continual basis. We ask patients for feedback, we ask locums about what we ought to improve, etc. So, as far as we are concerned, there is a continuous process of improvement and we try to live up to that as we would like to be regarded as serious health care providers. Unfortunately, inspections do not always provide a basis for sustained

improvement – there should be more focus on sharing good practices on the day of the inspection. At the moment, the GPhC is not even close to that!

Do you think there are any other benefits to your business from undergoing inspections?

P3: Not really. The terminology that has been used in the rating, from the patient point of view from the public point of view they need to change the wording but it does reflect the hard work that we put in to provide a good service to the patient. It is not recognised, the terminology the public do not perceive that as a good example.

P6: Reflecting on how we run the place, so, yes, of course there are benefits. Does not show up immediately but customers discuss it. That's when you know that people are aware of the good changes happening in practice.

P8: It gave a lot of confidence, because when you are doing those things you don't know and you cannot judge if you are doing well. It is good to know what you are actually doing. From a [...] point view and having done I, it field up gaps and knowledge that I did not know my staff had and helped me as well. So overall it was good

P12: Yes, we are following SOPs, it's more methodical and we are ready with our paperwork so it is good.

P16: For us, the inspection wasn't anything particularly hard to deal with. If our staff was asked about something, they would have something in their heads that we had talked about before. I suspect that there are a number of pharmacies where that isn't possible. People don't necessarily work to the same degree of involvement that we do. So I think for us there wasn't a massive benefit. But for other people, there could be. You can definitely see there's a difference in terms of how people work across the country. I think the new style inspection will do far more than the old one to actually correct that.

You've said in your survey response that [...] to improve the value of inspections and drive higher standards in patient care.

Can you explain your response in more detail? Anything else you'd like to add?

P3: In a way it does, in some clinical example you can benefit from advice or recommendation from the inspector. This does not need to be in the context of an inspection process because we are not aware. We were very fortunate on the day we had the inspection because we had 2 pharmacists. Single pharmacist having an inspection of four hours is quite detrimental to the service you actually provide on that day. That's a huge burden on one pharmacist.

P4: They should check how many items the pharmacy do and how many members of their staff are working there. Naturally the company wants to save money, so they try to keep staff at the minimum. Plus, at the same time, they want to increase the number of items to make profit. The staff is struggling with the workload. Then it has a negative impact for the customer.

P6: My approach is that I would make sure that people are warmed up, and make it clear the finality of a good inspection. [Him as an inspector would say] “But do not worry about it, if some things are not doing right, we will sit and discuss it and over the next few weeks, we will put everything right for you.” The inspector must be here to make sure the pharmacy is reaching adequate standards.

P12: It is very good. We do try to improve on the feedback. Whatever the feedback we get, we will definitely try to improve on it and as I said, it is a good way of learning for me because if I'm doing and if I'm getting to know things, it's a better way of learning for me.

P16: I think it would be possible for some pharmacies to actually just do things for the inspection and for it not to be a continuing improvement process. All inspections can be fiddled with, can be distracted by inappropriate use of words and demonstrations. I think the new style inspection is less biased than the old one and that it will be more true to life. I think that inspectors, once they are well-practiced, will be able to say: “we need to go back to this pharmacy again because there was something odd about it that didn't work quite well. I'm suspicious about that”. There have always been people who've fiddled with inspections and that there will always be.

3. Action-planning – ALL (I.E. INSPECTED AND NOT YET INSPECTED)

Have you had to develop an action plan following your most recent inspection?

P1: No, however we did have an action plan for a refit already in place because the pharmacy was getting busier and the current dispensing area was too small. I was also disappointed because the inspector did not want to review my plans for the refit, so I do not have any comments on it. So I submitted the plan to them and I said that I would like them to comment, because I only have experience in this pharmacy whereas they have experience in a lot of pharmacies. I thought their input would be beneficial but it was not forthcoming.

P2: Yes, we had an action plan but without any guidance to meet, we have to come up with our own. It was an issue of a damp in the basement. They did not tell us the maximum level of humidity they would be allow.

P3: No.

P4: If there is a good staff and the right number of staff, things are going on well.

P7: I did when we first had under the PCPs, we had inspections and they were every year. They used to come in and ask questions and talk about an action plan. At that time, it was quite new that standard operating procedures had come into play and there were too few gaps where we need to fuel. We were happy to address them.

P11: No

P12: There was no action plan as such as far as I'm aware. It is just a briefing by one of our senior pharmacists – I am not sure what she did exactly but she did come to our pharmacy

and she keeps telling us every now and then about the questionnaire. She has a hard copy, so if we have time, we can go to her and look at these questions again.

P15: No

P16: We scored “good”, so there wasn’t much action that needed doing. But it would have been nice to have some more in-depth feedback apart from the very broad feedback that we received. It would have been nice to get some details about “you did this and it was good; but if you did this it would be even better”. So rather than criticising what we are doing, the inspection should give opportunities for improvement.

Every section was marked as good apart from two satisfactory. There were a couple of comments on the satisfactory points, but it would have been nice to have comments on all of them about how we could improve even further.

P19: The last inspection we had was in [...] and there was not much we needed to do. Not with the GPhC one, we did not have to do anything. We were ok.

P20: I have already had one in place.

Would you say that action planning is an effective tool to sustain improvement? Could you explain?

P2: Not in relationship to that one. It has not improved anything, it is difficult change the level of humidity of a building within three days. It does not affect patient care.

P5: One thing I would say, it does not give much time to come up with an action plan. If it’s a small business they maybe cannot afford to have someone to do their job. So two weeks is just ridiculously short, it should really be a couple of months about action plan.

P6: Yes, I think it’s a very effective tool. The only problem I have is the use of computer, I do not like them. I am old-fashioned, everything is in my mind, I am practical and I show results. For me to sit down and log-on is quite cumbersome. I try to delegate that to another member of staff. You cannot teach an old dog new tricks. The newer in the profession over the past 10 years would find that easy.

P7: Yes, if an inspector comes in and finds that something should be done differently and achievable, of course I would definitely look after it.

P18: Yes, for sure. If the action plan is meant to help you raise internal standards, I’m all for it. But it is important to bear in mind that action plans can only be useful if it is about distilling out tangible changes the pharmacy is capable of making. It should not go overboard and require changes beyond what the pharmacy can make.

P20: I take a slightly different approach. I think, as I said previously, we try to adhere to requirements and what we should be doing on a day-to-day basis. Based on that we have

quite a rigid structure in place to make sure what we should be doing and what our plan is moving forwards. So, yes action plans are an important tool for continuous improvement.

You said in your survey response that [...] to improve the development of an action plan, or the focus of action plans. Could you explain your response in more detail? Is there anything else you'd like to add?

P6: The GPhC can certainly give more time and be accessible. The technician should be able to speak to the inspector regarding the shortfalls she or he may have. The inspector should be able to say, "You achieved this much, but from that point we can make sure that you go on that direction". It is basically like teaching a child how to walk. Being an inspector is not an easy job with a tremendous amount of work.

P20: Maybe a little bit clearer guidance in specific areas with respect to the regulations. There is so many regulations that we need to adhere to. What would be good, is having like a top 10 requirements of what needs to be in place. I understand that everything needs to be there. But if there was a top 10 list of things that probably were going wrong in the field that inspectors are coming across, we would appreciate it a bit more.

4. Reporting and publication

Do you think that reporting and/or ratings provide an incentive for continued improvement in the community pharmacy sector?

P1: Not the way it's set up for the moment, because you cannot really expect anything else than satisfactory.

P2: The ratings are too far apart from how it is perceived by the public. Poor is just meeting the minimum standard, then excellent. There is a lack in perspective and to understand why. It would be good to offer a significant step up.

P3: If they are about to publish the report I think they need to think strongly about the way the wording is. Because the all pharmacy sector will appear to be very mediocre.

P4: In a way, yes, if the pharmacy is doing well, there is nothing to report. If there are issues, yes, the report can help. It depends.

P6: I think it is good. The report makes the contractor aware if they fall short or if they have good standards. The point is as long as the inspector says, "You fall short on this point but there is nothing to worry about, let's work on this and look to get this right within three months". Just ask inspectors to be friendly.

P7: I don't think it should be done at all because that's quite worrying for a lot of pharmacies. What are they rating somebody on? On the size of the pharmacy? What would they be rating on? I would say they have to be careful on that. I would not agree on that at all. If the report was fair and there were valid points that needed improving, of course. But if it was nit-

picking, then no. I think if something needs improving then you have to improve it, no debate needed, you just go on with that.

P8: No, I do not think it does. It will play pharmacies off against each other. Plus something could happen that is not their fault. I do not think it's right to expose the pharmacies that need improvement.

P9: That has to be done in a carefully managed way. I think that the GPhC is still not clear as to how this report is going to take place. If the inspector is only looking at the point of view of the time that they are spending in the pharmacy and not taking into account how satisfied the public are with the service the pharmacy is providing, then that rating does not balance up necessarily. For example if the pharmacy has a poor rating according to the inspector but a very good patient satisfaction, then the two would not balance up and it will create a doubt in public's mind as to what that rating actually meant. The rating does not provide the public with a lot of information especially if the public is generally satisfied with the service.

P10: It depends on how competitive you are. Some pharmacies are happy with a "satisfactory" rating. I think patients tend to go to the exemplary pharmacy not the satisfactory pharmacy. So we strive to excel as we want to retain our customer base.

P11: Once we get a report, obviously it gives us an idea of where we are, with regards to the services that we are providing, so I think it should be an obligatory requirement to make sure that you put things in place, to act on that, in terms of the report. So, yes, it's definitely valuable. In terms of rating pharmacies it often happens that there are excellent pharmacies out there that are being given the label satisfactory, which doesn't really look good. When customers look at it, satisfactory means you just are just scraping through; I understand that we should not be overrated if we're not meeting the target set for that rating but I think that satisfactory as a term in itself sort of says to me average; I think if a pharmacy is meeting all the requirements but is not doing anything exceptional, then I think they should get a "good" rating. And if they are doing anything above and beyond that is really enhancing patients' service, they could be upgraded up to excellent or exceptional or whatever. Satisfactory doesn't say anything at all. If anything to put that on the wall in my pharmacy, my patients would think "yeah, just satisfactory". It shouldn't have to worry me if I was a patient in a pharmacy.

P12: Yes, definitely the reporting system in my pharmacy has been refined. We have people reporting the errors. We are using now using a more patient-centred approach.

P13: To a point. But I'm concerned that, along the way, people are forgetting that pharmacists are professionals – we would not be doing this job if we were not adhering to the standards and ensuring the safety of our patients. We're not the local McDonalds where obviously food hygiene needs to be monitored constantly. Most pharmacies strive to provide the best service because over time, they get to know their patients. There is a great patient-pharmacist rapport that is established over the years. So we will always keep up to the standards because our patients trust us. So, it's not the ratings themselves that motivate pharmacists to improve. It's the more our patients themselves.

P14: Yes, I do. We have regular meetings internally to discuss about safer care and patient safety and on how to improve our services and maintain good ratings. There are also external meetings – I've forgotten what they are called – that also require us to meet a certain level of standards and to achieve and maintain good ratings

P15: Yes, definitely. Because we are not always right so it's good to know, from the reports, the areas where we need to improve. This gives us an opportunity to discuss with our area manager and implemented the required changes.

P16: It goes two ways. I like the idea of ratings being used within pharmacy to help improve. What I would like to see is that people who aren't performing well are made to perform better. Rating them as unsatisfactory is going to make them perform better (otherwise people are going to stop going to their pharmacies). If inspectors judge a pharmacy as unsatisfactory, they should say, "These are the reasons why", "this is what you're going to do to improve it" and "I'll come back and judge you again and hopefully by then you will be satisfactory". That's absolutely fine and I think it's an excellent way of doing it.

But I'm nervous about publicising all of the ratings to the general public. I don't think that's a sensible thing to do. Everybody has an off-day (where they don't perform as well as they usually do). And you're always going to have a pharmacy which performs less well than the average because of external factors. I think the rating never ever gives the full picture. I can't think of a way where you could give the public a word or a rating and have a full picture of what's happening in the pharmacy.

P17: I think if that was the case, it would certainly make everybody pull themselves together a bit better. So I'm in favour of publishing results. It's a bit of a shame if the inspection happens on a bad day but unfortunately... I don't think the inspection on its own should be published. I think it should be included with other inspections (for example the annual customer satisfaction survey). I think it could be combined with that rather than just being a specific report on a specific day. Both the report and the rating should be published. The best example I can compare with is that of a catering establishment: if you've got less than a four out of five, I don't think anybody would go there.

P18: I don't think they do. They are artificial and are based on a snapshot of how things are being done in the pharmacy. Inspections, in my opinion, do not truly reflect the level of standards and service at the pharmacy. I don't think that performance is even measured objectively. So, overall, I don't think the current rating system is fair and I don't think it will help pharmacies improve.

P19: They should, yes, have a system of measurement and you would need that to quantify some things. Whatever standard are to be met, if you cannot attach a value to it, the standard does not mean much.

P20: Yes, it does provide an incentive, but it is just the amount of documentation and paperwork, which just creates extra burden. I do not think it is necessary.

What impact or added value do you think publishing reports and ratings would contribute to community pharmacies and patients in Great Britain?

P1: I think it will have a detrimental impact.

P2: Yes, when you get good feedback

P3: Not in the way they are classifying the pharmacies at the moment. I don't think it would have any added-value. If you are not in it, you don't understand. Inspectors do not appreciate the amount of work and the attention to detail that it required to satisfy the GPC or the local health board. And our added burden on tick boxes on top of patient care. Having the necessary piece of paper does not mean that it improves patient care.

P4: Not sure about that. Especially to put the name I do not think it's a good idea. It depends if the pharmacy has the support of the company.

P5: I think it is unfair, when you receive a satisfactory it just gives you the wrong impression, I think it should be "it passed" or "has not been checked through yet".

P6: There is a mixed-feeling here. Some people are quite OK with the publishing of the report but some of them would think it might have a negative impact on their business. After discussing with some colleagues, the report should only be done if you have not shown any kind of commitment to improving your standards. If you show commitment to improving your standards, I am sure, at your request, your report will not be published. Because I am sure that the GPhC would like to publish report showing progress for people to have faith in public pharmacies.

P8: More of a negative effect as mentioned above.

P10: I don't really think so. The names of the categories need improvement – they are not clear and can be misunderstood by general public. A satisfactory rating could, to them, imply that they will not get their prescription from this pharmacy. This will definitely adversely impact on certain pharmacies. I know this proposal is going into consultation so hopefully any feedback will be feedback to GPhC to make sure that it helps improve patient's safety but at the same time protect our businesses.

P11: With freedom of information and all these different legal aspects, if it needs to be made public then it needs to be made public, which is why I go back to saying I have concerns over the phrase satisfactory. If you meet the standards of the society, put in place obviously for good reasons, then hopefully the standards they require are good standards. So hopefully they should reflect that as a good pharmacy; do you know what I mean?

P12: If you are not doing something properly and someone tells you this is the way to do it, personally I would listen to them. I would gladly receive feedback and try and rectify things.

P13: I don't think people will necessarily think about them. My pharmacy business is very much client-based. As I alluded to earlier, I've built a solid relationship with my patients over these years. And ratings will not change this relationship. These ratings could potentially be more useful for the high-street pharmacies which tend to compete a lot against each other.

P14: Not easy to answer that. It could be a double-edge sword. If the inspection is a genuine reflection of the professionalism of the pharmacy, it could be a positive thing for the public to know. However, it would not be beneficial to pharmacies if these inspections are only based on performance on just one day than the overall performance over the course of the year. The consistency in performance should be acknowledged by inspection in their reports.

P15: I'm not sure how fair this is going to be. If you take two [...] branches, for instance, one could be rated good and another satisfactory. But we cannot really compare two branches who are following the exact same standards.

P17: I think it gives patients more confidence in which pharmacies they should go visiting. The pharmacies that fell below the standards won't be in business very long.

P18: I think the ratings are counterproductive and waste people's time. And what do they really mean to the public? Do they really increase confidence and trust? Just because a pharmacy is rated excellent does not mean patients are guaranteed a better service than if they were to go to a pharmacy that was rated good.

P19: Naming and shaming is the biggest drawback of the report. But on the other hand if something is being done very well it's good for the society to share it.

P20: I think it is a good thing. We perform very well and we have got nothing to hide. So I think it is a very good thing, to sort of detect the ones that are not (performing well).

Do you have any particular concerns about this proposal?

P1: The way the report will be viewed by external agencies would be detrimental to pharmacy. Because they are going to say that our regulatory body will only view most of the pharmacies they inspect as satisfactory.

P2: Because the headline of a pharmacy rating as poor does not take into account the fact that 95 per cent of the things were good but they have a damp in the basement that we do not use anyway. I am afraid we never get a good rate because of the humidity in the basement, in a building you cannot change things like that.

Also, the general public will never read the context of the rating given.

P3: I can see that smaller pharmacy in a rural area are struggling with getting staff and are missing resources.

P4: I am afraid that the company can use this report against the pharmacists and does not give any support.

P5: It could bring bad reputation to a pharmacy or can lead to think there is a mistake, if the doctor got it wrong or anything.

P9: It does not reflect the daily work. Every pharmacy starts the day wanting to provide the best services they can and it's a very dynamic situation with continuous pressure. We are working with a lot of pressure and yet providing a very good service. That has to be taken into account.

P10: Highlighted before.

P12: No

P13: Highlighted above

P14: A risky thing with this proposal is that, if the rating is not good, rather than the company actually instituting steps to improve things, there might be reprisals taken on the staff.

P16: It happens that sometimes you have a bad day, and then it gives a bad reputation to the pharmacy that does not reflect the overall picture of the services. And it's not just that. Even if you have a good day and you perform well and you get a good rating on the day: even that doesn't give the general public a complete picture of how we deal with every section of the business. Everybody has a section of specialism so there could be certain things in which a pharmacy is extraordinary good at and other things where it is only satisfactory at. Unless you give to the general public all of these different aspects, then you're not giving them the whole picture.

P19: No particular concern as long as they keep it open and complete

P20: Not really.

You've said in your survey response that [...] are certain improvements that could be made to inspection reporting to support their effectiveness in improving future standards of patient care. Could you explain your response in more detail? Anything else you'd like to add?

P1: They will have to change the grade and the criteria. There is a need for more grades between satisfactory, good and excellent. They should be more balanced. Sometimes I feel they are not working with us and I do not think they are really supportive. I cannot see the GPs or the dental profession put in this type of operation. I admit that we should all operate under the best possible standards but our inspectors are not really supportive.

P2: To rename the rating. I think the meeting the minimum standard rate could be called good and then the higher rating are even more positive. Poor must be really poor.

P3: Changing the wording.

P6: As long as there is a contribution from the GPhC and the inspectors to help contractors to get to the right standards. The contractors will take that help and would comply and make sure those changes are brought into actions. I think the contractor will realise the benefit that he is bringing to the business. If there is no kind of commitment to progress from the contractor, then of course the GPhC has the right to publish such report.

P7: Yes, I think so. From what I am reading because I have not had an inspection. I can only go by the comments made by other pharmacists. From what has been said it sounds quite worrying.

P9: I think the inspection itself is far too long, it's very time-consuming. The inspection could be done in a much more stream-lined manner so it can be done much quicker. From what we have read it can take up to 3-5 hours, which is way too long. We cannot function in that environment.

P10: None

P11: The inspector that came to us was very good, very thorough; he provided constructive criticisms which are obviously what they are there to do. An inspector is exactly what it says, he's here to inspect and look for things that may not be done properly, so I get the importance of it with regards to how they improve their service. I haven't got any suggestions other than the fact as I said that they should have asked the staff more questions about things they do day to day. I didn't think they had the chance to say anything really, any chance to really display how much work they do, because with a lot of the standards based around key roles in the pharmacy on a day-to-day basis that needs to be done and as the only pharmacist in this branch, I do delegate and trust my staff a hell of a lot, and they have to be extremely confident in me in order to do that, which they are and I just didn't feel the inspector allowed them to really say exactly what they do and not just what they do but how they actually think about what they are doing and put new measures in place to improve stuff ; that would be my main suggestion for how they can improve pharmacies outlook on the new inspection process.

P12: No I don't have any recommendation other than what we are doing now: it's become more patient centred and that's what our interest is.

P13: I think this proposal should be considered with care. We're not a food business (where the score-on-the-doors scheme tends to work really well and is important to ensure standards are maintained). And having worked in [...] before, I know that sometimes a trivial matter could lower the score significantly. For instance, your [...] may be excellent but inadequacy in record-keeping could lower your score. My fear is that this could happen in the community pharmacy sector as well. So despite the end-product being to standards, you could be unfairly scored lower only as a result of slight issues with paperwork or internal procedures.

P14: My only comment really is that it should be possible to organise inspections when the regular pharmacist is on duty. Inspectors would have a better picture of how things work. In my case, the pharmacy manager is not a pharmacist so they may not know where to look for information.

P16: More feedback would be very welcome. Other improvements points would be best practice communication... it's all about giving us more information to make us a better place. We are a [...] but we still don't get to see how other pharmacies work. We rely on other people to come to us and tell us, "This is how other people do it; it works for them; why do you not try it?" If we had feedback from an inspector who goes around all pharmacies, not just ours, there may be lots and lots of things that we can learn! Inspection would be a really good way of transmitting this information.

P19: The pharmacies offer a lot of other services. If the inspector has been in the community pharmacy before and knows all this stuff then he can apply a much more holistic approach instead of concentrating on patient and patient safety. It is not only about prescription medicine, there is a lot of stuff that is not on prescription but still available in pharmacies.

5. Perceived impacts

Through this new approach, the GPhC wants to create a cultural shift in community pharmacy practice – one that ensures community pharmacists meet the required standards but increasingly focus on outcomes and improvement and strive to put their patients and users of their services first.

Do you think the new approach is helping pharmacists achieve that?

P1: I believe pharmacy do that, it's something natural. Eventually, the report they are producing does not actually show that. They are asking for that and they put a tremendous pressure on us to do that, but the report produced does not show that.

P2: Not yet, possibly once every one has been inspected and the requirements are in place for 10 years or so.

P3: A more concise list of expectation, it's a big blurry for the moment.

P4: I do not know very much about this new approach compared to the other one. I have never done an inspection. Everything depend on how much support you have from the company. If they use this report against the staff and the pharmacy, it would be more pressure on them.

P5: I think yes, some need to be brought up to standard.

P6: I think this is a good approach. What I feel frustrated about is that you spent so many years studying at university and then we go to our pre-registration year and we build up our method of work and health care in our way. The point is with all the knowledge we have, our hands are so much tied we cannot do certain things that we are so much capable of.

P7: I have not heard of that, what is that? I thought that what we were doing already. When we are working you are looking at for the patient, that's what our role is.

P8: Yes, I think it does. I think the GPhC is more public health oriented so I think it can help the cultural shift.

P11: Yes. Obviously it's early days but I would agree it is helping in a way. The outlook on the inspection process is changing; but as I said spending more time with the staff to see if they understand the operating procedures they read, that should be made more robust in my opinion. Pharmacists are often tied up either by accuracy checking, if we can't delegate to a technician, and most of the time the government, particularly in [...], is pushing us to provide enhanced services and often advanced services at the same time so really the standards of the pharmacy and the housekeeping, record-keeping a lot of these are delegated to the staff... The pharmacist should be delegating to the staff more; when you get to the real crux of whether the pharmacy is performing and achieving good standards as I'm sure general pharmacists think they are, then they should be speaking to the staff more and seeing more what they are doing and as a result of that that would prove if pharmacy managers are doing their job well enough.

P12: Yes, definitely - it's more patient centred, we are achieving more professionalism.

P14: I'm not sure that inspections are necessarily achieving that. I think if we want a cultural shift, it's down to motivating the individual pharmacists. At the end of the day, in multiples, the primary focus is on income. And, as employees, our pay is not linked to performance or how we've treated patients and the degree to which we put their welfare first. Therefore, I don't see how inspections could change a company's attitude. But it should help the individual professionals to be more patient-focuses where they are given the time and resources to do that by the company work for.

P16: I think it's vital to bring about a culture shift in community pharmacy practice. Community pharmacies have to be completely focused on services. Dispensing is going to take a real backseat: it's going to be turned as a routine, almost boring part of the business. The thing that is going to be the focus of pharmacies of the next 15 to 20 years is services. That's going to involve not just pharmacists but also dispensers and checking technicians who will be trained to do all of the services; especially the services related to information gathering. The rest of their role should be made completely routine, and should be done very quickly and smoothly. Using inspections to demonstrate the skill level and the commitment level of those members of the team is a very useful first step. It's a very good way of making these people used to different approaches to pharmacy.

P18: No, because we are still faced with an immature inspection model.

P19: Create a lot of dilemma, people do not know where the line is between excellent and satisfactory or poor or ok. Those lines need to be refined because there is a big grey area.

I might think [...] shops are doing well but the inspector might have a different opinion because we have different perspective on what the shop should be doing. The measuring process at the moment is no specific.

P20: Don't get me wrong, I think it is a very good process. I think it makes sure that pharmacies run correctly and we are doing what we should be doing. I totally agree that inspections should occur. I own [...] of them. I know there are lots of colleagues that think this is a waste of time and we should just get on with our jobs. We take great pride in the way we run our pharmacies and we think we run them very professionally and in line with what GPhC would like us to do. But, the time taken to try to do all the documentation that is the difficulty primarily, not the time the inspector comes in. We have a lack of space in the pharmacy and having an extra body causes extra grief in a sense that we are having to run around people. We are just so busy, that people are just waiting but they want us to get prescriptions out for them. It does make a difficulty. But don't get me wrong, I think inspections are very, very well placed and they are required because I know what happens out in the wider pharmacy market. We welcome the inspections, but it is difficult when they do happen.

Do you think the new approach has the potential to drive better patient outcomes in the community pharmacy sector? If so, how do you see the sector in five year?

P1: It has the potential but I do not think the way they report it reflects the effort put in it, with all the stress and the pressure we are now being placed.

P2: Same as above in 10 years.

P3: No I don't think so. It's the framework for people falling very short from the expectation.

P4: I think only a pharmacy manager can reply to those questions.

P5: I doubt it, I think it's more about paper work. Things like the questionnaire is probably more patient focused because you see what they actually think. Whereas inspections is just bringing things up to standards but I do not know if the patient would actually notice that one.

P6: All I can say is it's an effort to drive it in that direction. But it is difficult to know if we will succeed.

P11: I think anything that improves our systems will eventually show in patient care even down to patient collection services, delivery services... [...]... all of which is leading to better patient care because it does encourage a more disciplinary approach, so yes I do agree with that if we are striving to improve our in-house systems, eventually the patients will see the benefits, yes.

P12: Yes. The sector in five years will be more manageable. All the reporting will definitely improve the pharmacy area.

P16: Yes, if we concentrate more on communication of best practice and try and encourage the inspectors to look for ways in which the non-pharmacist members of the team are using their skills to increase patients' benefits. For example, dispensers being involved in a stop-smoking treatment session. Or dispenser that run effective packing services to put medication into compliance aids for patients. That's what we need these people to be doing in order to stretch the benefits for the patients. Getting the inspectors to look for things like that is a good way to drive better patient outcomes.

P18: I think the extent to which pharmacies can offer better services, better quality and better patient outcomes is really dependent on contractual relationships they may have with commissioners. It all depends on how much commissioners would be willing to pay.

P19: It can as long as those lines are very clear. People have a target to work for. Five years for now, we will probably doing quite a lot of management and self-care compare to diagnosing.

The GPhC also wants more pharmacies to become actively engaged in achieving and sustaining compliance and improvement.

Do you think the new approach can help end the current "tick-box" approach to regulating community pharmacies? Why?

P1: Yes, it should be because people work in different way with different set of circumstances.

P2: Yes.

P5: The impression I get now is just more paperwork. I don't know until we have it.

P6: Yes, I would always recommend less paper-work because we do not have time.

P7: What's a tick-box approach? That's more paperwork and how are you achieving a good patient outcomes if you are increasing paper-load. We are already all those things.

P8: You've got the standards and so on, so it's not a tick-box approach

P11: I was never a fan of the tick-box approach anyway, because if an inspector comes in and the pharmacist has all the records and rest is in order, he'll just tick a box. That can be done anyway but patient beneficial systems have to be maintained constantly not just when an inspection is due. So these new standards do provide that. As I said, I'm all for it, I just think it just needs to be a little bit more robust in terms of allowing the staff to really explain what they do and why they feel it will be a benefit at the end of it.

P12: Yes, definitely.

P14: I would like to think so but I haven't seen any actual hard evidence that it is the case.

P16: It could but at the moment I don't think so: we're still stuck in that tick-box format. "Do you do that? Yes? That's great." "Tell me how you do that. Yes? That's great", "Do you do that? No? Oh no, that's a big cross". We're still at that stage rather than actually looking for ways to improve.

P19: Compliance with regards to the standards. Pharmacies practise that since it's part of the contract. The tick box is a burden, if you don't tick the box then you do not know if you met the standards or not. But this is not specific enough. You need to set specific target.

Do you think the new approach will provide enough freedom to pharmacists to decide how best to meet the standards while ensuring better outcomes for patients? If not, do you think this could still be achieved in the near future?

P1: In theory it should. I did not really think about it.

P2: Yes, I would say so

P5: Probably less. Maybe some places might have the opportunity to develop extra service but might not be available for us to offer them or paid for, so if that affects the rating that may not be fair.

P6: I think everyone is driving for improvement and safety but sometimes I try to find that some requirements are unnecessary. There must be room for contractors to give positive feedback.

P7: I am getting a bit confused because I thought we were already doing that. Why do we need more freedom to do that? We try to work in a safe environment for the safety of our and the patient. I have not got a clue of what you want me to say. I do not understand what they are trying to achieve. To me we should be already following those rules without justifying what you are doing. Because I am already doing that so I do not understand how that is the new approach.

P8: No, I don't think we do. Think we have got more regulation to work on.

P11: I wouldn't say that we have more freedom personally. I don't know if any of others have said this but I think that the biggest part of our job is constantly looking to improve internal procedures. We are constantly shaping our processes to fit the needs of the business every day. So I don't think we are allowed more freedom to do that. That has always been our job. I think pharmacy managers are embracing the standards and liaising it down to the staff and making them aware and giving them more ownership and responsibilities. When it used to be the old tick box exercises, it used to be the pharmacists that answered: "do they have everything in place? – Yes, they have", and the staff just milled around as usual. I think it didn't use to give a true perception of whether a pharmacy is working to improving the

systems. Whereas now, it would. But as I said, they really do need to make the staff questioning even more robust.

P12: I do in general. When we update our standard operating procedures there has to be a feedback from a pharmacy manager and all the pharmacists. They all sit together and get a newer version if things are needed. In a way they have got a bit of freedom.

P19: The new approach is not giving the pharmacists guidance, it's a bit too vague and too open. Just a bit of freedom is enough, but not too much.

Do you think the new approach can help pharmacists sustain improvement and quality/safety of their services to patients? Why?

P1: It does not help, it only says what you should do. That's done by [...].

P2: I would not agree with that, maybe in 10 years.

P8: Yes I think it does. I think it's different from what the society was, it's more up to date. It was helpful.

P11: Absolutely. Don't get me wrong, I'm responsible for everything that goes on on-site. But you can't be in control constantly all day so you have to trust in the staff. So to get a true reflection, the inspectors should question the staff. That would prove the pharmacy managers are doing their job by cascading the information down. So the pharmacy manager would read the set of standards and any new legislation that comes in and then we should be explaining this to our staff so they are aware of it. All we're trying to do is talk to it as a group. If there is something that needs to be done to meet the legal requirements, we'll talk about it as a group and more often than not the staff will come up with very good ideas as to how we can run with minimal workload, trying to maximize how we do the process. So I think if they make that side of the new approach to inspection more robust, then yes; definitely it's going to keep driving improvements in community pharmacies.

P12: Yes definitely. I have been emphasising on reporting errors and giving advice. It has so much improvement because of the changes in professionalism. It is not just normal pharmacy professionalism, it's a patient centred professionalism coming into being with all these regulatory bodies. I think it is all good in a way.

P16: No, I don't think there's any difference there. The standards are very well defined and you have to show that you do what's on the inspector's piece of paper.

I hope it will be achieved in the near future. Because if it is not achieved; it will be an opportunity wasted. We've got a big chance to make a real difference. It's a shame the inspection is still in the "yes, no, yes, no" format, because we should be looking much more at how, as a whole, the pharmacy makes its services safe.

P18: There should be a knowledge repository that pharmacists and their teams can refer to in order to understand how to meet the standards and achieve higher ratings. There should probably be evidence gathered from other inspections on how to meet the standards.

P19: Yes, because if you give them the best standards, then it's pretty obvious that all the services will be carry along with these standards. If everything is perfect, then the outcomes will be perfect as well.

Annex 8 Profile of non-community respondents

A total of 1,434 responses were received from pharmacy professionals working in various settings, other than community pharmacy. Most non-community pharmacy professionals could not discuss GPhC's new approach to regulating pharmacies in detail. This could be because not all pharmacies, in particular hospital pharmacies, are registered with and regulated by the GPhC. Hospital pharmacies are regulated by different regulatory bodies, including the Care Quality Commission (CQC). As such, the views of non-community pharmacy professionals refer to a community pharmacy sector as a whole, and are based on their previous working experience or general knowledge.

Responses from non-community pharmacy professionals account for 27 per cent of the total number of responses received to the survey (n=5,350). The overall response rate from non-community pharmacy professionals (i.e. as a proportion of the total population of participants contacted) is 3 per cent. In this analysis, only responses received from non-community pharmacy professionals are considered.

Profile of respondents

Geographic location

Non-community pharmacy professionals who responded to the survey indicated working in pharmacies located in all three devolved administrations, namely: England (n=1,182 or 82 per cent); Scotland (n=138 or 10 per cent); and Wales (n=58 or four per cent). About four per cent of respondents did not indicate where their pharmacy is located.

Role within the pharmacy

Among the non-community pharmacy respondents who identified their role, there was a relatively equal number of pharmacists (n=686) and pharmacy technicians (n=685).

Non-community pharmacy settings

Most respondents reported to be working in hospitals (n=939 or 65 per cent), followed by those working in primary care (n=271 or 19 per cent) and those involved in pharmacy education, training and research (n=164 or 11 per cent). The remaining five per cent of the respondents did not indicate the type of organisation for which they work.

Annex 9 Other regulators' approach to rating

Table A9.1 CQC's approach to ratings

The Care Quality Commission (CQC) is the independent regulator of health and adult social care in England. To help people make informed choices about their care and to encourage improvement in quality across the sector, CQC inspects health and social care services (such as care homes and hospitals for example) and then gives an overall rating, as well as a rating for five key questions on each core service inspected:

- Are they safe?
- Are they effective?
- Are they caring?
- Are they responsive to people's needs?
- Are they well-led?

The CQC has a four tier ratings system:



Outstanding - The service is performing exceptionally well.



Good - The service is performing well and meeting CQC's expectations.



Requires improvement - The service is not performing as well as it should and CQC has told the service how it must improve.



Inadequate - The service is performing badly and CQC has taken action against the person or organisation that runs it.

Inspections are carried out by teams that include trained inspectors, GPs, nurses, practice managers and trained members of the public who have experience of care. CQC has published a handbook setting out how the inspections are implemented and how inspectors determine the rating following an inspection. Ratings are published on CQC's website, together with inspection reports. By law, care providers have to display the ratings given to them by the CQC.

In the past inspections were carried out on an annual basis. Under the new performance rating system, the frequency of inspections has been reviewed: services judged 'outstanding' are re-inspected within two years; while 'good' services are revisited within 18 months. On the other hand, services judged to be 'requiring improvement' are seen within a year of their previous inspection; while those rated 'inadequate' are re-inspected within six months.

Sources: CQC website, available at: <http://www.cqc.org.uk> ; [Community Care](http://www.communitycare.co.uk/2014/04/11/top-rated-services-go-two-years-without-inspection-cqc-reform-plans/)
<http://www.communitycare.co.uk/2014/04/11/top-rated-services-go-two-years-without-inspection-cqc-reform-plans/>

Table A9.2 FSA's approach to ratings

To help consumers choose where to eat out or shop for food and encourage businesses to improve hygiene standards, the Food Standards Agency inspects places where you can eat out, eat away or where you shop for food. The rating given to a business reflects the standards of food hygiene found on the date of inspection. Inspectors look at how well businesses meet the law by looking at:

- how hygienically the food is handled;

- the condition of the structure of the buildings;
- how the business manages and records what it does to make sure food is safe.

Ratings range from 0 to 5:



0: Urgent improvement necessary.

1: Major improvement necessary.

2: Improvement necessary.

3: Generally satisfactory.

4: Good.

5: Very good.

If the rating “5” is not achieved, the inspector explains to the person who owns or manages the business what improvements need to be made and what action they can take to improve.

Inspections are carried out by local authorities in Great Britain in partnership with the Food Standards Agency.

Ratings can be found on the FSA’s website. However, businesses do not have to display their rating.

FSA inspectors might undertake routine inspections. Inspections can also be carried out if a complaint was received. The frequency of inspections depends on the type of business and its previous record. Some premises might be inspected at least every six months, others much less often.

Sources: FSA website, available at: <http://ratings.food.gov.uk>

Table A9.3 HSE’s approach to ratings

The enforcement of health and safety law is split between the Health and Safety Executive (HSE) and Local Authorities (LAs).

To help local authorities to formulate their relative intervention priorities i.e. allow them to better target their other interventions on the basis of risk, HSE (along with LAs) gives a score from 1 (full compliance) to 6 non-compliance) to four different elements of a business’s health and safety performance:

- confidence in management;
- safety performance;
- health performance;
- welfare compliance gap.

HSE operates a four category risk rating system based on a business’ health and safety performance:

A: High risk (Score of 5 or 6 on any risk)

B1: Medium risk (Score of 4 on any risk)

B2: Medium risk (Score of 3 on any risk)

C: Low risk (No score greater than 2)

The frequency of inspections depends on the nature of the work. Inspections may be less often, for example, if the work environment is judged ‘low risk’ (e.g. a predominantly administrative office). But if there are certain

areas of a workplace or specific activities that are judged 'high risk' or changing rapidly, more frequent inspection may be justified (e.g. a construction project).

Sources: HSE website, available at: www.hse.gov.uk

Table A9.4 Ofsted's approach to ratings

Ofsted is responsible for the inspection of schools.

A handbook available on the UK Government's website provides instructions and guidance for Ofsted inspectors. Grade descriptors focus on:

- the overall effectiveness;
- the quality of leadership in and management of the school;
- the behaviour and safety of pupils at the school;
- the quality of teaching in the school;
- the achievement of pupils at the school;
- the effectiveness of the early years provision;
- the effectiveness of sixth form provision.

The descriptors provided are not to be used as a checklist. Inspectors should adopt a 'best fit' approach which relies on their professional judgement; i.e. when observing teaching, inspectors look at and reflect on the effectiveness of what is being done to promote learning: they are not looking for specific or particular things.

Ofsted has a four tier ratings system:

- 1:** Outstanding
- 2:** Good
- 3:** Requires improvement
- 4:** Inadequate

Inspection reports can be found on Ofsted website. The pattern and frequency of inspections is expected to change under Ofsted's new inspection framework. The highest-rated schools, i.e. schools in the "outstanding" category, will no longer face routine inspections. These schools will only be re-visited if results decline or parental concerns prompt an inspection. "Good" schools will face inspections at least every five years; while "satisfactory" schools will be inspected at least every three years. On the other hand, "inadequate" schools will be more closely monitored, with a re-inspection likely within a year.

Sources: Ofsted website, available at: <https://www.gov.uk/government/publications/school-inspection-handbook> ; Teaching Times <http://www.teachingtimes.com/news/ofsted-inspection-framework.htm>.