

Consultation on developing our approach to regulating registered pharmacies

Analysis of the effects on equality

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1. Aims and purpose of the project/policy

- 1.1 This paper analyses the equality and diversity implications of proposed changes to the inspection of registered pharmacies and the publication of inspection reports in order to give effect to the Public Sector Equality Duty under section 149 of the Equality Act 2010. This requires the GPhC to have due regard to each of the statutory objectives, including the need to:
- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under this Act;
 - advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it;
 - foster good relations between persons who share a relevant protected characteristic and persons who do not share it.
- 1.2 Conducting an analysis of the equality and diversity implications of our proposals also helps to ensure that we are not acting in a way that is incompatible with a Convention right¹.
- 1.3 Assessing the equality, diversity and inclusion impact of our policy development work is about being proactive in facilitating opportunities for people with the widest possible range of experiences and perspectives to engage with and influence our values, our culture, our strategy and the work we do. We aim to take an inclusive approach to working with users of

¹The Human Rights Act 1998, Section 6

pharmacy services, registrants, stakeholders and people affected in any way by our policy decisions.

- 1.4 This EIA includes an overview of the work we have completed to inform our understanding of the equality and diversity dimensions of the proposed changes; and, to consider the potential impact on these groups. This has been informed by our quantitative and qualitative analysis of responses to the consultation; the available data and / or evidence relating to, and our engagement with, a wide variety of stakeholders.
- 1.5 We have updated the analysis throughout the different stages of the policy development process, including pre-consultation, during the consultation and engagement period and post-consultation.
- 1.6 The analysis is intended to assist Council in considering whether the changes to the regulatory framework and approach to regulating pharmacies and our proposals should be approved.
- 1.7 At all stages of the process, we have considered how best to engage with equality groups, and equality and diversity issues have informed our policy development plans from the outset. We have sought to identify and mitigate any adverse impact on pharmacy owners, pharmacy professionals and people using pharmacy services, as well as groups of people with a protected characteristic. We have also considered how the proposed changes can help make a positive impact on these groups.
- 1.8 In preparing this analysis, we have considered all the statutory objectives under Section 149 of the Equality Act.
- 1.9 Additionally, given that these proposals have a potential impact on registered pharmacies and how they operate as businesses, we have also included an annex to this analysis examining the regulatory impact of the proposals on this occasion. Information from the impact assessment carried out by the Department of Health (DH) in 2015 for the Rebalancing medicines legislation and pharmacy regulation programme: Registered pharmacy standards and related matters² and the DH's Report on responses to the consultation³ in 2016 has been included here, as well as information from the specific questions in the formal consultation about the regulatory impact of our proposals.

Policy context

- 1.10 As the regulatory body for pharmacy one of the roles of the GPhC is to assure the public that registered pharmacies are safe to provide services. One of the ways that the GPhC does this is to use its Inspectorate. The GPhC has a team of Inspectors who visit registered pharmacies to make checks on them to make sure that they are meeting the standards for registered pharmacies that the GPhC sets.

2 Impact assessment: Rebalancing medicines legislation and pharmacy regulation programme: Registered pharmacy standards and related matters

3 Report on responses to the public consultation on the Pharmacy (Premises Standards, Information Obligations etc.) Order 2016

- 1.11 Standards set by the previous pharmacy regulator were prescriptive and inspection at that time, before 2010, focussed on compliance with those prescriptive standards and the legal requirements around controlled drugs and other relevant legal provisions.
- 1.12 In 2010, the GPhC began by adopting many of the standards from the previous regulator as a transitional measure. In 2012, after a period of extensive engagement and consultation the GPhC developed and adopted new outcome focussed standards for registered pharmacies⁴. The formal consultation ran from February to May of 2012. And the final version of the standards came into effect in September 2012.
- 1.13 To inspect pharmacies against the new standards, a new prototype inspection model was developed. The new inspection model was introduced in November 2013. This new model used a new framework and approach of “show and tell” to cover all the pharmacy’s services, involve the whole pharmacy team and promote professionalism by encouraging the exercising of professional judgement to meet the standards.
- 1.14 The GPhC published an update paper in February 2015 to restate its core principles in this area of regulation, and to commit to update the new model on the basis of feedback received and the evidence available.
- 1.15 The GPhC commissioned independent research⁵ to evaluate the new approach to regulating pharmacies. The findings were published in a report in October 2015. The research said that the new approach was generally working well, and highlighted some areas that could be improved.
- 1.16 Following changes to the law in May 2018 the GPhC was given new powers. These included new powers of enforcement and the ability to publish inspection reports. In light of these changes we set out our six proposals on how we intend to modify our approach to the regulation and inspection of registered pharmacies in a consultation document, and sought views on what we propose to do. We also carried out pre-engagement with patient focus groups and held several round table meetings with other stakeholders and commissioned a survey of the public.
- 1.17 Inspection outcomes - One of the elements of the new inspection model introduced in 2013 was a system of ratings for each pharmacy to indicate how it performed against the 26 standards. An overall judgement of either poor, satisfactory, good or excellent was assigned to each pharmacy after being inspected. The introduction of this rating system was to promote and drive improvement by introducing a scale of performance which pharmacy owners could continuously improve on and sustain.
- 1.18 This system of ratings was one of the areas highlighted by the research commissioned in 2015 that could be improved. The rating system was an area that many internal and external stakeholders involved with inspection had provided feedback on, and agreed would benefit from some clarification.

⁴ **Standards for registered pharmacies**

⁵ **Evaluating the GPhC's approach to regulating community pharmacies Final Report to the General Pharmaceutical Council ICF Consulting Services**

1.19 Following on from this research and feedback from inspectors and pharmacy owners and superintendents who have had their registered pharmacies inspected, we have proposed to make some changes to the way in which pharmacies are rated. We propose to no longer have 4 categories to rate the pharmacy overall. There will only be two possible overall outcomes of the inspection. The pharmacy will either be “standards met” or “standards not all met”.

1.20 Sharing examples of notable practice - The standards for registered pharmacies are grouped under 5 principles which broadly cover the areas of governance, staff, premises, pharmacy services and equipment and facilities. We propose to differentiate the performance of pharmacies at an inspection at principle level to identify notable practice. The findings for each principle will be one of four options: “standards not all met”, “standards met”, “good practice” or “excellent practice”. Areas of notable practice will be highlighted and available in a knowledge hub that will be searchable by anyone, the public and the pharmacy sector alike. This proposal is aimed at driving improvement by sharing good practice and making learning easily accessible.

1.21 Moving to unannounced inspections - Currently advanced notice is given that an inspection will be carried out at a registered pharmacy in the following 4-6 weeks after the notice is given. The GPhC is proposing to change this and make inspection visits unannounced. The public have indicated that this is what they prefer and how they expect inspections to be carried out. It gives a closer representation of how the public experiences that pharmacy on any given day and will more closely reflect whether the pharmacy is meeting the standards every day.

1.22 Requiring all standards to be met to receive an overall “standards met” outcome - Another change is that if any standard is found not to be met the pharmacy overall will also be “standards not all met”. Under the current model a standard could be “not met” and may still be judged as “satisfactory” overall. Patients expect that if a pharmacy receives a “standards met” outcome that they will have met all of the standards. The current standards have been in place for over 5 years now and pharmacy owners and pharmacy staff should now be familiar with the standards and what is expected to meet them.

1.23 New types of inspection - We propose to improve our approach to inspections to make sure that we are agile and responsive. We propose to use three types of inspection which we can use in different situations – routine, themed and intelligence led. This will enable us to be more responsive when we need to be and to look at specific issues in pharmacy and services in greater detail, whilst still providing the necessary assurance to the public that we will still routinely inspect every registered pharmacy.

1.24 Publishing inspection reports - We now have the power to publish inspection reports. We have previously stated that we would publish reports once we had the power to do so and the intention is that we start doing this in the first part of 2019. The 2015 research said that publishing reports would help pharmacy owners to improve services and empower patients and the public and the pharmacy sector. The Department of Health in its Impact Assessment said that the publication of reports is a key driver both to improve public confidence and public choice and to reward good performance and highlight poor performance, without imposing costs. The DH also said that by publishing reports it would mean that consumer expectations would be met in more familiar ways to them. The DH views are based upon the

experiences of another regulator publishing their inspection reports (the Care Quality Commission – CQC).

1.25 We consulted on our proposed changes to the way in which we regulate registered pharmacies and the publication of inspection reports between 17 May 2018 and 9 August 2018. We then analysed the consultation responses, and incorporated any changes to our approach and proposals.

1.26 Our Council will consider the analysis, updated approach and proposals in November 2018 and if it approves them, then the proposals and the publication of reports will come into effect in the first part of 2019.

1.27 If approved, the proposals, which are set out in the consultation analysis report in detail, will allow the GPhC to:

- modify the way it regulates registered pharmacies in the future, (by using different types of inspection - routine, themed and intelligence led)
- publish inspection reports
- be more open and transparent to the public and the wider pharmacy sector about inspections, and
- share the learning gathered from inspections more widely amongst the pharmacy sector and others through the knowledge hub (and through the publishing of reports).

1.28 Approval of the proposals will mean that our approach to regulating registered pharmacies will continue to provide assurance to the public that pharmacies are safe to provide services and will encourage pharmacy owners to reflect on the services they provide, and the way they operate their pharmacies, and make improvements.

1.29 In carrying out this analysis, we have considered the potential equality and diversity implications of the new proposed regulatory framework and the new process of publishing inspection reports.

2. Review of available information and/or data

Developing our evidence-base

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

2.2 We used the research from an independent evaluation (see paragraph 1.15 above) of our approach to inspections to inform our proposals. The research involved analysing 5,350 responses to an online census of the experiences of community pharmacists and pharmacy technicians to the new inspection model. There were also (20) qualitative semi-structured interviews with GPhC inspectors and stakeholder organisations about particular aspects of inspections and to unpack individual responses to the online questionnaire and explore in depth the issues of relevance to the study. Existing research and information was also

gathered and reviewed at that time by the research organisation. The research can be seen in full at the link found via paragraph 1.15 above, in the footnote for this paragraph.

- 2.3 We used feedback from patient focus groups held in England, Scotland and Wales at the end of 2017 to inform the development of our proposals, with respect to the information that the public would want to have access to, and how they would like the information about inspection reports and the inspection outcome to be presented, and made available, to them.
- 2.4 The key findings at the focus groups were that there was strong agreement that the inspection report (both the summary version and the detailed version) should be publicly available. There was broad agreement that the reports need to be easily accessible and searchable online using a number of options (postcode, pharmacy name, type of pharmacy etc.). The overall outcomes of met and not met were said to be clear and simple to understand. The draft reports were found to be clear, easy to read and contained the information they would expect. Comments were made on the necessity of the notable practice section to be in the summary report, and therefore we moved this section to the detailed report instead. The focus groups were positive about the format, content and tone of the draft reports and broadly understood the need to identify variations in performance at principle level to support improvement. They thought that the descriptions of the four possible options of how well a pharmacy had done under each principle was clear and easy to understand.
- 2.5 We used data from our quality assurance procedures, including information from our feedback surveys submitted by pharmacy owners and members of the pharmacy team about the inspection process, to make improvements to the current inspection model.
- 2.6 We have taken into account the feedback from round table events with stakeholders as well as other regular meetings with stakeholders and events throughout 2017 and 2018.
- 2.7 We have also used the data we gathered through our online consultation. We asked several questions about the potential impact of our proposals on several different groups: pharmacy service users; pharmacy owners; the pharmacy team; and those with protected characteristics.
- 2.8 The key findings from the formal consultation with respect to the impact of the proposals were that the majority of respondents thought that the changes would have both positive and negative impacts on the different groups asked about. With respect to groups with protected characteristics the majority of respondents thought that there would be no impact on any of these groups or individuals within these groups. Some respondents indicated that there may be impact on groups that may not have access to online resources, or are not fully IT literate. They highlighted that this may include some older people. And similarly accessing written reports online was highlighted as a potential difficulty for people with learning difficulties, language or literacy challenges.

- 2.9 There were some comments about the potential negative impact on the pharmacy team as a result of the publication of poor inspection results, in particular where members of the pharmacy team were pregnant or were disabled due or had a mental health condition, and whether this may cause additional pressure.
- 2.10 Several respondents thought that these proposals would have a positive impact on everyone using pharmacies, including those with protected characteristics, as it would encourage improvement in services, openness and transparency.
- 2.11 The key findings from the YouGov survey of 2,040 members of the public, which were broadly about our proposals generally, were that around three quarters of adults asked thought that moving to unannounced inspections would provide the public with more assurance that pharmacies will meet standards for safe and effective care, (79 per cent); that the wording “standards met” and “standards not all met” is clear, (77 per cent); were supportive of the publication of inspection reports, (77 per cent); supportive of the publication of improvement action plans, (73 per cent); and the display of the outcome of the inspection in the pharmacy, (80 per cent).
- 2.12 Other findings from the YouGov survey were that the biggest factor in people deciding which pharmacy to use was convenience, (79 per cent). Only 3 per cent of people asked said that the outcome of the last inspection would influence their choice of which pharmacy to use. 45 per cent of adults said that they would be likely to visit a pharmacy that had a “standards not all met” outcome, whilst 39 per cent said they would not be likely to do so. However, when told about the improvement action plan those proportions changed. Knowing that an improvement action plan would be in place where a pharmacy had a “standards not all met” outcome 68 per cent of people said that they would be likely to visit that pharmacy again and 19 per cent of people said that they would not be likely to do so. 47 per cent of people agreed that where one standard was not met that should result in an overall outcome of “standards not all met”. 26 per cent of people disagreed with that and 27 per cent of people neither agreed or disagreed or didn’t know.

Legal framework

- 2.13 In developing our proposals we gave due regard to our statutory objectives under Section 149 of the Equality Act 2010 and we believe that the proposals align with our over-arching objective which is the protection of the public⁶.
- 2.14 Our proposals about the publishing of inspection reports are provided for under the Medicines Act 1968, the Pharmacy Order 2010⁷, the Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016⁸ and the associated commencement Order of

⁶ The Pharmacy Order 2010, Article 6(1)

⁷ The Pharmacy Order 2010, Article 9(3)

⁸ **The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016**

Council 2018⁹. We believe our proposals are in line with what the legislation intends and allows us to do.

2.15 Overall, we believe that the proposals are reasonable, fair and justified as good and beneficial for both pharmacy owners and the quality of service that pharmacy users will receive.

3. Screening for relevance to equality and diversity issues

Does this project/policy have any relevance to (delete as appropriate)

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

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

4.1 Yes, full EIA required.

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

4.3 If approved, the proposed changes to the new regulatory framework and approach will apply to all registered pharmacies, and will affect all pharmacy owners, those pharmacy professionals working in registered pharmacies, (the majority of registered pharmacy

⁹ **The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2016 (Commencement) (England, Wales and Scotland) Order of Council 2018**

professionals) and will also have impacts on the public using pharmacies and pharmacy services.

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

5. Consultation / Involvement

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

- a. We commissioned patient focus groups at the end of 2017 (which were broadly population representative and included people with protected characteristics under the Equality Act 2010) to discuss our proposals. Focus groups were convened in England, Scotland and Wales to ensure that we heard views from across the different nations about the publishing of inspection reports, and the format and content of the inspection reports. We used the feedback to inform and develop the draft inspection report format.
- b. At the Inspectors' meeting in April 2018 there were sessions dedicated to the proposed changes and an opportunity to discuss the practical implications of some of the proposals.
- c. Consultation was launched via a press release¹⁰ on 17 May 2018.
- d. Emails to all registrants, superintendents, owners, pharmacy organisations and professional bodies, Clinical Commissioning Groups (CCGs), health professionals and systems regulators, and patient organisations with a link to the online survey, concurrent with the launch (potential respondents were invited to respond via an online survey, by email or by post). Hard copy, large font and other language versions of the document were available on request.
- e. Article in the GPhC online publication 'Regulate'.
- f. Provision of a consultation 'tool kit'¹¹ with a newsletter, powerpoint presentation with speaking notes, and pre-written twitter posts to help stakeholders promote the consultation through their networks
- g. Follow up emails to registrants and stakeholders on 24 July and 6 August 2018 as a reminder to respond to the online consultation.
- h. Members of staff on hand to answer any questions throughout the consultation process
- i. Round table consultation events with stakeholders were held in London, Cardiff and Glasgow in June 2018.

¹⁰ Press release: [**GPhC consults on proposals to develop approach to regulating registered pharmacies**](#)

¹¹ Registered pharmacies consultation tool kit: [Registered pharmacies consultation toolkit - newsletter copy](#) ; [Registered pharmacies consultation toolkit - presentation](#) ; [Registered pharmacies consultation toolkit - speaking notes for toolkit presentation](#) ; [Registered pharmacies consultation toolkit - social media guide](#)

- j. We commissioned a YouGov survey of 2,040 members of the public representative of the British population, in August 2018, to ask their opinions on the proposals we had put forward in the consultation around unannounced inspections, the changes to the overall outcome of inspections, publication and the likelihood of them visiting a pharmacy and what informs their decisions on which pharmacy to use. Fieldwork was undertaken between 8 and 9 August 2018. The survey was carried out online. The figures have been weighted and are representative of all GB adults (aged 18+).
- k. Inspectors gave 22 presentations to stakeholders at Local Practice Committee (LPC) meetings.
- l. 1-2-1 meetings were held with:
 - Association of Independent Multiple Pharmacies (AIM)
 - Association of Pharmacy Technicians UK (APTUK)
 - Avicenna
 - Care Quality Commission (CQC)
 - Community Pharmacy Scotland
 - Community Pharmacy Wales
 - Company Chemists' Association (CCA)
 - Department of Health and Social Care (DHSC)
 - NHS England
 - National Pharmacy Association (NPA)
 - Numark
 - Pharmacists' Defence Association (PDA)
 - Pharmaceutical Services Negotiating Committee (PSNC)
 - Professional Standards Authority for Health and Social Care (PSA)
 - Royal Pharmaceutical Society (RPS)
 - Scottish Government Health and Social Care Directorate
 - Welsh Government
- m. Multiple trade and national press articles relating to the consultation.

Patient focus groups

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

5.3 We sought views on the format and content of the publishable reports, as well as other aspects of the proposals in relation to access and availability of information and inspection reports. (See paragraph 2.4 above for detail on the key findings.)

5.4 We also commissioned a YouGov survey of 2,040 members of the public. (See paragraphs 2.11 and 2.12 above for detail on the key findings.)

Pharmacy focus groups and roundtables

- 5.5 As described above, we held three large roundtable meetings in London, Cardiff and Edinburgh in June 2018 with multiple stakeholders. The roundtable meetings were attended by pharmacy stakeholders including representatives from professional membership bodies for pharmacists and pharmacy technicians; multiples and independent pharmacies; NHS organisations; public health organisations; community and hospital pharmacy; and other stakeholders
- 5.6 We also held several roundtable meetings with other pharmacy organisations and stakeholders as opportunities arose to do so, as detailed above in paragraph 5.1.k.

6. Date, method and results of consultation

6.1 The consultation on developing our approach to regulating registered pharmacies was open for 12 weeks (17 May 2018 – 9 August 2018). As part of the consultation survey, we included several questions about the broad impact of the proposals in the consultation. The following questions were relevant to the impact on groups with a protected characteristic [listed in Section 3]:

- Question 19: “What kind of impact do you think the proposals will have on people using pharmacy services?”
- Question 22: “Do you think anything in the proposed changes would have an impact – positive or negative - on certain individuals or groups who share any of the protected characteristics listed above” [in Section 3]
- Question 23: “Do you think there will be any other impact of our proposals which you have not already mentioned?”

We analysed the responses provided to these questions below. And they are integrated in section 8 of the EIA. Further analysis can be found in the consultation report¹² itself.

6.2 In total we received 812 written responses. The number of respondents who identified themselves as individuals was 685 and those saying they were responding on behalf of organisations numbered 127. 5 responses were from individuals and organisations writing more generally about their views. There were 807 responses to the online survey. Of these 807:

- All 807 respondents answered questions 19, 20, 21 and 22.
- 161 respondents provided comments to question 23.

6.3 The results for Question 19 were as shown below:

¹² Developing our approach to regulating registered pharmacies: Consultation report

- 273 respondents provided further comment

What kind of impact do you think the proposals will have on people using pharmacy services?	N and % individuals	N and % organisations	Total
Positive impact	184 (27%)	26 (21%)	210 (26%)
Negative impact	54 (8%)	13 (11%)	67 (8%)
Both positive and negative impact	325 (48%)	61 (50%)	386 (48%)
No impact	86 (13%)	16 (13%)	102 (13%)
Don't know	35 (5%)	7 (6%)	42 (5%)
Total N of responses	684 (100%)	123 (100%)	807 (100%)

6.4 The comments about the impact on people using pharmacy services fell into four main themes. It was thought that our proposals would drive up quality and lead to improvement in the quality of services for all pharmacy users and increase public trust and confidence in pharmacy and would empower patients by giving them information to make choices. Some commented that the proposals would not make much difference about which pharmacy people would choose to use as they would rely on their own personal experiences and convenience rather than on reports online. A few people said that the publication of reports may mislead or confuse the public and cause those who were not able to access alternative pharmacy services concern.

6.5 The results for Question 22 were as shown below:

- 137 respondents provided further comment

Do you think anything in the proposed changes would have an impact – positive or negative – on certain individuals or groups who share any of the protected characteristics listed above?	N and % individuals	N and % organisations	Total
Yes	113 (17%)	17 (14%)	130 (16%)
No	380 (56%)	75 (61%)	455 (56%)
Don't know	191 (28%)	31 (25%)	222 (28%)
Total N of responses	684 (100%)	123 (100%)	807 (100%)

6.6 The impact on people with protected characteristics was that there were mostly no adverse impacts predicted. There were comments that there might be adverse effects on the elderly, those with learning difficulties, language and literacy issues as well as IT literacy and access in relation to being able to access inspection reports published online. Employees with mental health issues, and employees who were pregnant were suggested as groups who could be potentially affected by pressure resulting from unannounced inspections and the publication of poor results. However, there were many comments about how these proposals would have a positive impact for pharmacy service users generally as services will be improved. Other positive impacts that were mentioned were increased transparency and accessibility for pharmacy service users.

6.7 The results for Question 23 were:

- 161 respondents provided comments to question 23 about whether they thought there would be any other impacts of our proposals which have not already been mentioned

6.8 There were no other impacts (on people with protected characteristics) identified in these responses. Approximately half of the respondents leaving comments said that they did not think there were any other impacts, or did not know. The impacts mentioned in these comments echoed those mentioned in the answers to the previous impact questions and are incorporated into those sections.

6.9 The impact questions asked in the consultation were broad. And from the detailed comments received we have incorporated them in the relevant equality areas in section 8 below, or in the regulatory impact annex in section 11 below, as appropriate and relevant.

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

6.11 We analysed the responses provided by respondents to the consultation. They are integrated in section 8 of the EIA.

6.12 Please refer to our analysis of consultation responses for further detail on the methodology, and the results.

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

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

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

7.3 Issues relating to the regulatory impact have been detailed in Section 11 below, the Regulatory Impact Annex.

8. Full impact assessment

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

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

8.1 Respondents to the consultation identified internet use as a potential barrier to some older people accessing inspection reports which will be published online. The latest results from the Office for National Statistics (ONS) on Internet Users in the UK¹³ say that virtually all adults aged 16 to 34 years were recent internet users (99 per cent) in 2018, compared with 44 per cent of adults aged 75 years and over. According to Age UK¹⁴, internet use among older age groups has increased substantially over the last five years, but many are still non-users.

8.2 From the data from the equality monitoring questions in the consultation, which were optional to answer and not compulsory, the ages of respondents were evenly distributed between the 25-34 years, 35-44 years and 45-54 years ranges with a similar number in the last two age ranges together (the 55-64 years and 65+ years age range). A total of 519 people answered this question, (26 skipped this question). A small percentage did not answer the question and preferred not to say which age group they were in.

What is your age?	Response per cent	Response Total
16-24 years	1 per cent	7
25-34 years	20 per cent	102
35-44 years	23 per cent	119
45-54 years	25 per cent	129
55-64 years	17 per cent	89
65+ years	6 per cent	32
Preferred not to say	8 per cent	41

8.3 From the data from the equality monitoring questions at the patient focus groups, which were optional to answer and not compulsory, the ages of attendees were as shown below. A total of 57 people answered this question, (2 did not answer this question).

What is your age group?	Response per cent	Response Total
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¹³ Office for National Statistics (ONS): **Statistical Bulletin: Internet users, UK: 2018**

¹⁴ **The Internet and Older People in the UK – Key Statistics**

16-24 years	8 per cent	5
25-34 years	12 per cent	7
35-44 years	21 per cent	21
45-54 years	8 per cent	8
55-64 years	14 per cent	14
65+ years	3 per cent	2
Did not answer	3 per cent	2

8.4 From the data from the equality monitoring questions in the YouGov survey, of 2040 people, the weighted base of age ranges were as shown below, (due to the weighting, the response totals have been rounded up and add up to 2041):

Age group	Response per cent	Response Total
18-24 years	11 per cent	229
25-34 years	15 per cent	307
35-44 years	17 per cent	347
45-54 years	16 per cent	333
55+ years	41 per cent	825

8.5 One of our proposals involves the publishing of inspection reports. Several respondents identified that the publishing of reports online would not be accessible to all, for instance older people who may not have access or the IT skills to find and read the reports. And that therefore this group may be disadvantaged compared to younger age groups who would have access to this information in a format that they are familiar with and routinely access. The ONS report for 2018 highlighted that the gap is closing between older and younger groups accessing the internet. They ONS say that since the survey began in 2011, adults aged 75 years and over have consistently been the lowest users of the internet. In 2011, 20 per cent of adults aged 75 years and over were recent internet users, rising to 44 per cent in 2018. And recent internet use in the 65 to 74 age group increased from 52 per cent in 2011 to 80 per cent in 2018, closing the gap on younger age groups.

8.6 Our proposals should be beneficial for all pharmacy users, including older people. Publishing inspection reports will drive improvements in services. The benefits will be seen by older people who cannot access the reports in the same way as other pharmacy users will see the benefits, whether they are able to access the reports or not. All age groups up to the age of 74 access and use the internet often.

8.7 Some respondents commented that the lack of mobility would limit the choice of older people to choose a different pharmacy, if the one they use had received an outcome of “standards not all met”. Our monitoring and regulation of pharmacies does not leave pharmacies to remain in a position where they do not meet our standards. Through our

various enforcement mechanisms pharmacies must take steps to meet the standards within a certain time. And the progress of improvements is monitored by the inspection team to ensure that they are made. 85 per cent of pharmacies meet all the standards at inspection. Once the enforcement mechanisms are put in to place, 99 per cent of pharmacies meet all the standards within time limits set. From the YouGov survey 45 per cent of people responded that they would be likely to continue to use a pharmacy that had received an outcome of “standards not all met”, (39 per cent said that they would not). However, when told about how we use improvement action plans those proportions changed. Taking these plans into account and that we would be monitoring them, 68 per cent of people responded that they would be likely to continue to use a pharmacy that had received an outcome of “standards not all met”, (19 per cent said that they would not).

8.8 We will work with support organisations such as Age UK and Carers UK to highlight to harder to reach older people that inspection reports will be available online if they wished to see them, and assist such organisations with their usual channels to improve access to online resources. Local Healthwatch organisations will also have access resources and be able to assist. We are in the process of looking at how we could make the most of communication as a powerful regulatory tool to help enable the safe and effective practice of pharmacy. This includes communicating directly with the public and forging links with patient and public representative groups to make them more aware about the standards of quality they should expect from pharmacy and educating them on what good looks like and potential risks. This means they will be able to make informed choices. And, in doing so we will be harnessing them to be part of minimising risks to patient safety and driving improvements in quality. To be effective we will be engaging and communicating more to ensure we understand their needs, views and concerns.

8.9 We do not envisage any other significant equalities impact of the proposals in relation to age.

Disability – consider environmental, social and attitudinal barriers

8.10 From the data from the equality monitoring questions in the consultation, which were optional to answer and not compulsory, 4 per cent of people said that they considered themselves disabled. 87 per cent said that they were not disabled and 9 per cent of respondents preferred not to say. A total of 512 people answered this question, (33 skipped this question). From the patient focus groups 24 per cent considered themselves disabled, 69 per cent said that they were not and 7 per cent preferred not say or did not answer this question.

8.11 The Results from the Family Resources Survey for financial year 2016 to 2017, providing information on income and circumstances of UK households¹⁵ published by the Department of Work and Pensions in March 2018, say that 22 per cent (13.9 million) of people reported a disability in 2016/17. This uses the core definition of disability in the Equality Act 2010, where

¹⁵ **The Results from the Family Resources Survey for financial year 2016 to 2017, providing information on income and circumstances of UK households**

a person is considered to have a disability if they report a long-standing illness, disability or impairment which causes substantial difficulty with day-to-day activities.

8.12 We heard that some people with disabilities (in particular, learning difficulties and those with literacy and numeracy difficulties) might find it difficult to access resources online, such as inspection reports. As part of the feedback we have sought to assess the impact of our proposals on people with disabilities.

8.13 We will also consider any requests for copies of any inspection reports in another language and format (such as large print or Braille) and provide these.

8.14 Several respondents considered that our proposals could affect staff with disabilities working in a pharmacy, potentially placing additional pressure on those with a disability due to a mental health issue.

8.15 Whilst we have heard these concerns, a large number of comments said that there would be no negative effects on this group, or could not foresee any potential negative impacts on people with disability. There were also multiple comments which expressed the view that our proposals would be beneficial to all pharmacy users including those with disabilities, by empowering pharmacy users, being open and transparent and encouraging and incentivising pharmacies to improve.

8.16 We do not envisage any other significant equalities impact of the proposals in relation to disability.

Gender reassignment – consider impact on transsexual and transgender people including bullying, harassment and discrimination issues not least ensuring privacy of data to avoid disclosure of gender history.

8.17 In the consultation it was suggested that our proposals may lead to better services and delivery of services for certain groups, for example gender reassignment individuals. And in particular, that this may lead to pharmacies providing better confidentiality for pharmacy users at the pharmacy counter and when picking up prescriptions.

8.18 Other comments expressed the view that our proposals would be positive and beneficial to all pharmacy users and groups. Groups that fear discrimination are able to exercise more informed choice without having to personally visit the pharmacy.

8.19 We do not envisage, nor have evidence to suggest, any significant equalities impact of the proposals in relation to gender reassignment.

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

8.20 From the responses to the consultation, and the focus groups, we did not hear of any issues relating to marriage or civil partnerships. This means we cannot fully assess whether our proposals are likely to have differing impacts on anyone in these groups.

8.21 However, we do not envisage, nor have evidence to suggest, any significant equalities impact of the proposals in relation to marriage or civil partnership.

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

8.22 In responses to the consultation, a few comments suggested that additional pressure would be placed on pregnant members of the pharmacy team working in the pharmacy or on pregnant pharmacy owners. And that there may be more pressure on pregnant pharmacy owners and pregnant pharmacy employees of publishing inspection reports (especially if the reports show an outcome of “not all standards met”) and unannounced inspections.

8.23 We do not envisage, nor have evidence to suggest, any significant equalities impact of the proposals in relation to those who are pregnant or on maternity leave.

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

8.24 In the UK, 87 per cent of people are white, and 13 per cent belong to a black, Asian, Mixed or Other ethnic group. As part of our feedback received we have sought to assess the impact of our proposals on people of different race.¹⁶

8.25 From our consultation response equality monitoring form, which were optional to answer and not compulsory, regarding the race of respondents, the majority of respondents identified themselves as British, (56 per cent); and others as Indian, (13 per cent); Other white background, (6 per cent); African, (4 per cent); Pakistani, (3 per cent); and Chinese or Chinese British, (2 per cent). 10 per cent of respondents preferred not to say. A total of 517 people answered this question, (28 skipped this question).

8.26 The patient focus group identified themselves as British, (64 per cent); and others as Asian or Asian British, (16 per cent); and Black or Black British, (10 per cent). 3 per cent of respondents did not answer.

8.27 The percentage of different races who responded were more highly represented here than in the general population of the UK. This gave ample opportunity for this group to identify any potential impacts.

8.28 Quite a few respondents felt that language would be a barrier to accessing information online, in particular, in relation to published inspection reports, (see also section on Welsh language scheme below, section 10).

¹⁶ [Ethnicity facts and figures](#)

8.29 Many online tools (for example Google translate) now exist which enable the translation of text and documents by people wishing to access resources themselves. Many of these are available free of charge also. Our inspection reports are currently written in plain English and will continue to be written in an accessible way when they are published, which will make it easier for them to be translated.

8.30 We will also consider any requests for copies of any inspection reports in another language and format (such as large print) and provide these.

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

8.31 We heard from a range of respondents, some identifying with a religion and those having no religion, but none raised any particular concerns. From our consultation response equality monitoring form, which were optional to answer and not compulsory, 41 per cent of respondents said that they were Christian; 23 per cent said that they had none; 8 per cent were Hindu; 7 per cent were Muslim; 3 per cent were Sikh. (14 per cent preferred not to say.) A total of 515 people answered this question, (30 skipped this question).

8.32 We do not envisage, nor have evidence to suggest, any significant equalities impact of the proposals in relation to different religions or beliefs or none.

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

8.33 From our consultation response equality monitoring form, which were optional to answer and not compulsory, 49 per cent respondents were female, 44 per cent were male, 1 per cent replied other and 6 per cent of respondents preferred not to say. A total of 522 people answered this question, (23 skipped this question).

8.34 From our patient focus group, 65 per cent of attendees were female, 32 percent and 3 per cent did not answer. The YouGov survey reported that 51 percent of respondents were female and 49 per cent were male.

8.35 The patient focus group highlighted that our proposals would affect carers, as more frequent users of pharmacy services. The majority of those with caring responsibilities are women, according to Carers UK¹⁷ and the 2011 Census. They say that almost 6 in 10 (58 per cent) of carers at the last Census (2011) were women. Caring falls particularly on women in their 40s, 50s and 60s, with 1 in 4 women aged 50-54 having caring responsibilities for older or disabled loved ones, compared to 1 in 6 men. Women are also overrepresented in those providing 'round the clock' care, with 60 per cent of those caring for over 50 hours a week being female. This was identified as a group that would be more interested in the quality of the pharmacy services being provided and more likely to look for information and inspection reports on pharmacies before choosing which one to use.

¹⁷ Carers UK - [Response to Women and Equalities Committee Gender Pay Gap Inquiry 2015](#)

8.36 As mentioned above in paragraph 8.8, we are in the process of looking at how we could make the most of communication as a powerful regulatory tool to help enable the safe and effective practice of pharmacy. This includes communicating directly with the public and forging links with patient and public representative groups, such as Carers UK, to make them more aware about the standards of quality they should expect from pharmacy and educating them on what good looks like and potential risks.

8.37 We think that our proposals will impact this population positively, empowering them and giving them more information and transparency and detail about the pharmacy they may choose to use.

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

8.38 From the data from the equality monitoring questions in the consultation, which were optional to answer and not compulsory, 81 per cent of people said that they heterosexual / straight; 3 per cent said they were a gay man; less than 1 per cent said that they were a gay woman / lesbian; less than 1 per cent said they were bisexual or other. 15 per cent preferred not to say. . There was no indication that our proposals are likely to have differing impacts on anyone in relation to sexual orientation.

8.39 However, we do not envisage, nor have evidence to suggest, any significant equalities impact of the proposals in relation to sexual orientation.

9. Welsh Language Scheme

9.1 A Welsh version of the consultation document was provided. This ensured that Welsh speaking stakeholders had the opportunity to provide input.

9.2 We will also be publishing inspection reports in Welsh, for pharmacies in Wales.

10. Monitoring

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

10.1 This analysis is intended to assist Council in considering whether the changes proposed to the way we inspect pharmacies should be approved.

10.2 Once the new approach has been approved and implemented, we will continue to gather feedback and data on the performance of the inspection cycle and evaluate the approach to ensure that it continues to provide the necessary level of assurance about the safety and suitability of pharmacies to provide services to the public.

10.3 We will continue to use any feedback in the refining of the inspection model and the way in which we regulate pharmacies. And we will monitor any other equality concerns that emerge and how we will mitigate against them.

10.4 We will also continue to work with the GPhC's Equality, Diversity and Inclusion (EDI) Leadership group to update and review this Impact Assessment, as and when appropriate.

What is the timetable for monitoring, with dates?

10.5 The performance of the inspection cycle will continue to be monitored on a quarterly basis by our Council.

10.6 There will continue to be periodic quality assurance reviews and audits every 6 months on inspection reports.

10.7 The feedback from pharmacies and pharmacy owners will continue to be requested from pharmacies at the end of each inspection and will also be reviewed periodically (quarterly or every 6 months), to ensure that the new approach is working effectively.

11. Regulatory impact questions in the consultation

11.1 The analysis in this annex focuses on the regulatory impact of the proposals detailed in the consultation. This analysis is separate to the analysis of the Equality, Diversity and Inclusion (EDI) issues set out above in the previous sections.

11.2 The consultation on developing our approach to regulating registered pharmacies was open for 12 weeks (17 May 2018 – 9 August 2018). As part of the consultation survey, we included several questions about the impact of the proposals in the consultation: In total we received 812 written responses from 127 organisations and 685 individuals in the survey. 5 responses were from individuals and organisations writing more generally about their views. There were 807 responses to the online survey.

11.3 From these 807 responses to the online survey:

- All 807 respondents answered questions 20 and 21.
- 161 respondents provided comments to question 23.

11.4 The questions concerned with the regulatory impact were:

- Question 20: “What kind of impact do you think the proposals will have on the owners of registered pharmacies?”
- Question 21: “What kind of impact do you think the proposals will have on the pharmacy team?”
- Question 23: “Do you think there will be any other impact of our proposals which you have not already mentioned?”

11.5 The results for Question 20 are shown below:

- 262 respondents provided further comment

What kind of impact do you think the proposals will have on the owners of registered pharmacies?	N and % individuals	N and % organisations	Total
Positive impact	133 (19%)	20 (16%)	153 (19%)
Negative impact	119 (17%)	25 (20%)	144 (18%)
Both positive and negative impact	355 (52%)	68 (55%)	423 (52%)
No impact	32 (5%)	5 (4%)	37 (5%)
Don't know	45 (7%)	5 (4%)	50 (6%)
Total N of responses	684 (100%)	123 (100%)	807 (100%)

11.6 The responses to the consultation indicated that the impact on owners was likely to be both positive and negative. Views were expressed that the proposals could increase the pressure that owners felt, and require resources to improve practice, conditions, staffing and patient safety. This could be a drain on resources already under pressure for other reasons, but would ultimately have positive consequences for patients and the public. There were many comments which said that the proposals would encourage improvement and better services to be provided and would lead to good pharmacies getting better and poorer pharmacies improving.

11.7 Part of the reason that views on the potential impact were mixed was that it was thought that it would be dependent on how the pharmacy was performing. Good and positive reports could bolster team morale and the pharmacy's performance, the owner's pride in their pharmacy as well as local recognition and wider enhancement of the pharmacy profession amongst the public. However, if the pharmacy was not performing well and not meeting standards then potentially it was thought that this could be negative and have an economic impact on failing pharmacies if the public used this information to choose which pharmacies to use, or service commissioners used this information. Rather than prompt pharmacies to improve, negative results may demoralise the team, prompt more complaints. Although there were comments that the negative impacts would be short lived and would ultimately lead to the necessary improvements and improved standards.

11.8 Unannounced inspections were described as being potentially negative as it would not allow the owner to prepare for an inspection and there could be patient safety concerns if the pharmacy was very busy and thought that the inspection could be disruptive. Inspectors generally do not currently specify a date and time for their inspection visit, and are also able to inspect without any prior notification being sent. The inspection team are all registered pharmacy professionals and understand the importance of minimising any impact (disruption and interruptions) on the pharmacy team during the inspection, especially when they are interacting with pharmacy service users. There are positive benefits for the public if the pharmacy owner needs to make sure that their pharmacy is meeting all the standards every day, continually, rather than just for a temporary period of 6 weeks when they have been notified that the inspector could visit. This was mentioned in several comments as being potentially relevant, and beneficial, in relation to staffing levels.

11.9 Sharing good practice and the knowledge hub were mentioned many times as being a positive proposal for owners as it will enable them to see examples of practice to emulate.

11.10 The results for [Question 21](#) are shown below:

- 291 respondents provided further comment

What kind of impact do you think the proposals will have on the pharmacy team?	N and % individuals	N and % organisations	Total
Positive impact	138 (20%)	18 (15%)	156 (19%)
Negative impact	149 (22%)	27 (22%)	176 (22%)
Both positive and negative impact	367 (54%)	68 (55%)	435 (54%)
No impact	10 (1%)	5 (4%)	15 (2%)
Don't know	20 (3%)	5 (4%)	25 (3%)
Total N of responses	684 (100%)	123 (100%)	807 (100%)

11.11 As described above, in paragraphs 11.6 – 11.8, the views were that there would be a mixed impact largely dependent on how the pharmacy was performing and the outcome of the inspection. If the pharmacy received a positive outcome then there would be a morale boost for the pharmacy team, a more positive environment and positive impact with further improvements in services for pharmacy users. And there would be willingness to share and publicise the good outcome.

11.12 If the result was a negative outcome, then there would be reluctance to want that outcome to be widely known. The negative outcome could potentially have a negative effect on the pharmacy team (irrespective of how widely this outcome was shared with others outside the pharmacy team). This could demoralise and demotivate staff, and lead to a downward spiral. At the same time, this may be short lived if the pharmacy could make the necessary improvements. This may require an increased workload for, and on, the pharmacy in the short term, but would be beneficial for the pharmacy team (and pharmacy users) in the longer term.

11.13 Positive impacts on the pharmacy team were thought to be that the pharmacy team would be clearer on what they needed to achieve and focus them more on the standards and meeting them. This would lead to better working conditions and be helpful for highlighting where services would need to be improved, and support was needed to meet the standards. The pharmacy team could also learn from other reports and examples of good practice. This could motivate the pharmacy team as they will not want a negative outcome of an inspection. They will want to be meeting all the standards.

11.14 Comments about the negative impacts were that this would add to the administrative burden on pharmacies and their teams. Negative reports could be demoralising and could have an impact on the business. The pharmacy team may be stressed and anxious about unannounced inspections, however as described above in paragraph 11.8 this is not significantly different to the current position as far as the pharmacy team would be concerned. The pharmacy team could be put under pressure to meet the standards which may increase their workload.

11.15 The results for Question 23 were that:

- 161 respondents provided comments to question 23 about whether they thought there would be any other impacts of our proposals which have not already been mentioned

11.16 There were no other (regulatory) impacts identified in these responses. Approximately half of the respondents leaving comments said that they did not think there were any other impacts, or did not know. The impacts mentioned in these comments echoed those mentioned in the answers to the previous impact questions, and have been incorporated into those sections

12. Other relevant regulatory impact assessments and reports

Department of Health – Rebalancing medicines legislation and pharmacy regulation programme

12.1 In February 2015 the Department of Health issued a UK consultation¹⁸ on behalf of the four UK Health Departments to seek views on pharmacy related draft Orders being made under the powers in section 60 of the Health Act 1999.

12.2 One of the draft Orders being consulted on was, at the time, called The Pharmacy (Premises Standards, Information Obligations, etc.) Order 2015. This included a provision to enable the publication of inspection reports. It included the following section and question in the consultation document, (on pages 38 and 39):

Publication of GPhC reports and outcomes from pharmacy premises inspections

124. It is proposed to amend Article 9 of the Pharmacy Order 2010 to provide for publication of GPhC reports and outcomes from pharmacy premises inspections. Those changes will make clear that if such a report includes personal data it is assumed under data protection requirements that such information can be published as a result of the GPhC's pharmacy regulation function (paragraph 20 of the draft Order).

Question 13: Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

12.3 A regulatory impact assessment was carried out by the Department of Health at that time, entitled: Department of Health – Rebalancing medicines legislation and pharmacy regulation programme: Registered pharmacy standards and related matters (IA 2 of 2)¹⁹. This impact assessment contained the following information regarding the provisions which would amend the Pharmacy Order 2010 and enable the publication of inspection reports and the outcome of the inspection (on page 27):

Pharmacy Order 2010 – Pharmacy owners

¹⁸ [Rebalancing Medicines Legislation and Pharmacy Regulation: draft Orders under section 60 of the Health Act 1999 – Consultation document](#)

¹⁹ [Department of Health – Rebalancing medicines legislation and pharmacy regulation programme: Registered pharmacy standards and related matters \(IA 2 of 2\)](#)

Article	Requirement	Replacement	Regulatory impact	Cost impact on pharmacy businesses	Comments
Article 9	Clarifies that the GPhC can publish registered pharmacy inspection reports, which may include an account of the outcome of the inspection.	N/A	Clarification of existing expectation so that results of inspections are transparent and publicly available and can be published and shared more widely e.g. with other regulators, NHS commissioners etc. No impact on the volume or frequency of inspections is expected.	Cost neutral	In England, publication of inspection reports by the Care Quality Commission (CQC) is a key driver both to improve public confidence and public choice, and to reward good performance and highlight poor performance, without imposing costs. Retail pharmacies generally do not have to register with the CQC. The new arrangements will enable GPhC to meet consumer expectations in ways that are more familiar to them.

12.4 The Department of Health’s information indicated that making this change would be cost neutral to pharmacy businesses, would not have any impact on the volume or frequency of inspections carried out.

12.5 This Impact Assessment also described several positive impacts from publishing inspection reports and the outcome of inspections: Transparency of results, sharing information and learning more widely, improving public confidence and choice, rewarding good performance and highlighting poor performance.

12.6 Following the public consultation, in February 2016 the Department of Health published its Report on response to the public consultation on the Pharmacy (Premises Standards, Information Obligations etc.) Order 2016²⁰. It included the following section about question 13 in the consultation document, (on pages 13 and 14):

Publication of GPhC reports and outcomes from pharmacy premises inspections

Consultation Question 13:

Do you agree with the changes to provide for publication of GPhC reports and outcomes from pharmacy inspections?

<i>Responses</i>	<i>Agree</i>	<i>Disagree</i>	<i>Not Answered</i>
<i>Number</i>	<i>113</i>	<i>11</i>	<i>35</i>
<i>%</i>	<i>71%</i>	<i>7%</i>	<i>22%</i>

What we proposed

44. It is proposed to amend Article 9 of the Pharmacy Order 2010 to provide for publication of GPhC reports and outcomes from pharmacy premises inspections. Those changes will make clear that if such a report includes personal data it is assumed under data protection requirements that such information can be published as a result of the GPhC’s pharmacy regulatory function.

What we heard

45. Out of 159 respondents, 124 answered this question. Of these 91% supported the proposal for the publication of GPhC reports and outcomes of pharmacy inspections.

46. Those who responded positively remarked upon the approach being in line with that adopted by other system regulators, such as the Care Quality Commission and that it supported transparency. However, it was vital that the inspection, rating and reporting system is fair and fit-for-purpose.

47. It was suggested that the reports should be accompanied by an appropriate explanation to aid understanding, by members of the public, of the regulations and standards.

48. The concerns expressed by those who did not agree with the proposal and some who did, included that further engagement with stakeholders is needed; inspection grading needs to be addressed; that an appeals process should be available before the publication of the report; and that piloting of the new arrangements should be considered.

²⁰ Report on response to the public consultation on the Pharmacy (Premises Standards, Information Obligations etc.) Order 2016

Quotes:

“The more information re Pharmacy inspections and reports is made public the better. The information should be made available via the NHS Choices website”

“This change would be in line with the approach operated by other system regulators such as the CQC”

“Promotes openness and transparency and accountability”.

“We also agree that where relevant personal data needs to be included in reports that this will be in

accordance with data protection requirements. Consistency in reporting the outcomes of pharmacy

inspections will be even more important when reports are published. GPhC may consider a pilot

approach to assess the impact of this change”.

12.7 Support for publication of inspection reports was clear in this group of respondents.

12.8 The concerns raised by those that did not agree have been, and are being, addressed.

There has been engagement with stakeholders on the format of reports, the proposals and the grading system. An appeals process before publication is in place and is being piloted. And pilots will be introduced for various proposals before being fully implemented.

12.9 There is further information in this report about whether respondents agreed with the impact assessments that the Department Health carried out. 94 per cent of those that answered that question agreed with the costs and benefits assessments for the pharmacy premises standards proposals.

The King’s Fund research on the Impact of the Care Quality Commission on provider performance: room for improvement?

12.10 This report²¹ on the CQC’s impact describes eight ways in which regulation can affect provider performance. It shows that regulation has an impact before, during and after inspection and through interactions between regulators, providers and other key stakeholders.

12.11 One of the eight areas described is Informational Impact whereby the regulator collates intelligence and puts information about provider performance into the public domain or shares it with other actors who then use it for decision making (e.g. commissioning, patient choice).

²¹ Alliance Manchester Business School and The King’s Fund research on the Impact of the Care Quality Commission on provider performance: room for improvement?

12.12 Published information seems to provoke action primarily amongst the providers of services themselves and particularly in response to a poor outcome. The public has a right to know how services are performing, yet the research seemed to indicate that they did not use this information to choose services (the exception being social care users and their families choosing a care home, who did refer to reports to help them make a decision about service providers to avoid). If the public took a similar approach to choosing which pharmacy to use this will drive improvement and encourage pharmacies to meet the standards.

13. Monitoring

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

13.1 This analysis is intended to assist Council in considering whether the changes proposed to the way we inspect pharmacies should be approved.

13.2 Once the new approach has been approved and implemented, we will continue to gather feedback and data on the performance of the inspection cycle and evaluate the approach to ensure that it continues to provide the necessary level of assurance about the safety and suitability of pharmacies to provide services to the public.

13.3 We will continue to use any feedback in the refining of the inspection model and the way in which we regulate pharmacies. And we will monitor any other regulatory impact concerns that emerge and how we will mitigate against them.

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

13.4 The results from the consultation, the patient focus groups, and the YouGov survey have informed the approach we intend to take to regulating pharmacies, how we will inspect, what we will publish and how we will publish inspection reports, improvement action plans and learning and examples of notable practice.

13.5 The issues identified through this analysis will be taken into account when deciding on the approach and the implementation of our proposals.

What is the timetable for monitoring, with dates?

13.6 The performance of the inspection cycle will continue to be monitored on a quarterly basis by our Council.

13.7 There will continue to be periodic quality assurance reviews and audits every 6 months on inspection reports.

13.8 The feedback from pharmacies and pharmacy owners will continue to be requested from pharmacies at the end of each inspection and will also be reviewed periodically (quarterly or every 6 months), to ensure that the new approach is working effectively.

13.9 We will continue to update and amend this Impact Assessment as and when appropriate.