

Consultation on developing our approach to regulating registered pharmacies

Royal Pharmaceutical Society response

In the [Introducing new types of inspection](#), section, we describe the changes we plan to make to the types of inspections we carry out.

- 1. Do you think the three types of inspection (routine, themed and intelligence-led) will:**
 - **provide more assurance that pharmacies are meeting our standards?** Yes
 - **enable us to be more agile and responsive to risks or changes in pharmacy or healthcare?**
Don't know
 - **help to drive improvements through identifying and sharing good practice?** Yes

The RPS believes that these three types of inspection will provide more assurance that pharmacies are meeting the required standards. The intention of these types of inspection is to provide assurance that there is a more effective process in place that recognises good practice whilst also identifying areas for improvement and we support this. Using intelligence to guide inspections will mean that pharmacies requiring extra support are visited more often and that the GPhC can be more flexible in its approach.

It is difficult to assess the impact that the proposed changes will have on the effectiveness of the GPhC at this early stage, although we expect that the GPhC will be more responsive and willing to modify practice, but until this is applied in practice it is difficult to know.

It will be interesting to see how the themed approach progresses.

We welcome the fact that the GPhC will identify and share good practice as we are aware that a lot of useful information is not currently shared.

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

The Intelligence gathering inspections need to be approached in a way that ensures they are not seen as persecution of the pharmacy. A clear standard should be set for the level of intelligence or concern that triggers an inspection. Potential conflicts of interest on the part of those raising concerns will also need to be considered.

In the [unannounced inspections](#) section, we describe our plans to move from announced to unannounced inspections as a general rule for routine and intelligence-led inspections.

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

Yes

Moving from announced to unannounced inspections will ensure that every day practice is reflected at the time of inspection. We agree that unannounced inspections should be implemented as a general rule as you are then more likely to determine how the pharmacy operates on a daily basis. However, it would be good to see the evidence base upon which the decision to change from routine announced inspections to unannounced inspections has been made.

The pressure felt by the responsible pharmacist and the pharmacy staff during an inspection can be significant. The inspectors need to be aware during unannounced visits that the responsible pharmacist's main priority will be patient safety and that they will need to concentrate on their pharmaceutical care and supervision duties and may not be able to commit the time to the inspection that it requires.

GPhC should be mindful of the impact this change could have on the wellbeing of the pharmacy workforce and monitor this if implemented.

Having unannounced inspections will also better reflect staffing levels as pharmacies will not be able to just increase staffing levels for those few weeks during which an inspection may occur.

However, the GPhC need to be aware that a locum pharmacist working in a pharmacy just for that day may not have all the required knowledge to be able to answer some of the questions that are focused more on the organisational aspects of the pharmacy. Although we are aware that other members of staff may be available to answer the questions.

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

No, with proviso below

5. Please describe the other instances we should consider.

Every pharmacy should be included, with the proviso that should things be chaotic and an inspection would be dangerous or a risk to good service or patient care in the opinion of the responsible pharmacist. The GPhC could then ask them to close at the time of the visit or just make observations on the day and return at later time, unannounced, to discuss things further with the responsible pharmacist.

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

The GPhC may need to be more responsive should a situation arise that requires on site attendance by a GPhC inspector in order to observe or witness a certain situation such as a registrant affected by substance misuse or alcohol whilst responsible for a pharmacy.

[In the Changes to the inspection outcomes section of the consultation document we describe the changes we plan to make to the outcomes of an inspection.](#)

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

No.

We do not agree that having two categories will make it easier for the public to understand the outcome of the inspection. There is an issue that if standards are not met pharmacies will not be given time to meet the standards before this is announced. Members of the public may not feel comfortable using a pharmacy that has not met the standards. Standards met (provisional) or not all standards met might be a another category where a pharmacy has areas of improvement that need attending to where generally they are good but have to sort out some areas of improvement within a timescale (at which point they either meet the standard or not). There could be a risk with this binary approach that those pharmacies who are generally good get pushed into not met (or vice versa). This approach only works if the standards are absolutely crystal clear and the criteria for reaching them are described in a binary way (yes/no).

There is a risk of undermining the public's confidence in the pharmacy if they have received a 'standard not met' rating but the reason for this is something minor. This could be perceived by the public as a more serious issue than it actually is. This could be mitigated if the overall standard for the pharmacy is clearly published alongside the individual standards' achievements, for example pharmacy meets standards overall but has not met standard x or y.

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

Having these sub divisions will provide a means of further categorising pharmacies and enable GPhC to focus their attention on those pharmacies that require it more. It also enables differentiation between those who have perhaps just not met one standard and those pharmacies where several standards have not been met. However, using the terms good and excellent practice could be difficult to determine and should perhaps be replaced with 'exceeds standards'. This provides an incentive to move beyond 'met' or 'not met' and is more tangible than 'good practice'.

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

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

Yes, but note caveat.

You can only classify a pharmacy as meeting standards if all standards have been met. However, as we have mentioned previously this approach can be misleading as an excellent pharmacy may fail because it has not met one of the standards fully. Please see our response to Q7.

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

Please see our response to Q7 and Q8. We have concerns that the difference between 'met' and 'not all met' is too subtle and may give a misleading impression that a pharmacy is badly failing.

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

The RPS welcomes the approach proposed but the impact of these changes need to be monitored and assessed on a continual basis. Any refinements identified need to be adopted and incorporated into the process.

The RPS have developed a range of professional standards which provide another benchmark and assessment of practice to drive improvement. These should be included in or referenced in post inspection feedback where relevant.

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

12. Do you think we should publish inspection reports?

Yes.

We believe that inspection reports should be published. The publication of reports also demonstrates GPhC's commitment to safeguarding and protecting the public and patients when accessing registered pharmacies or receiving services provided by a registrant.

13. Do you think publishing inspection reports will:

- **provide greater transparency about the outcome of an inspection?** Yes
- **provide assurance to users of pharmacy services that pharmacies have met the standards?**

Yes

- **enable the pharmacy sector as a whole to use the information in the reports to improve?**

Don't know

The inspection reports will enable members of the public to see how well the pharmacy they utilise is performing and may influence their decisions as to which pharmacy they go to for their pharmacy services. The reports can also provide information on the community pharmacy sector as a whole.

The use of information by the pharmacy sector will be dependent on how the intelligence and information is presented and shared as pharmacists will not have time to go through individual reports.

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

You can see samples of the new report templates on our website.

In principle these seem appropriate but until they are applied in practice it is difficult to assess them.

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

Don't know

A summary of the action plan may be useful as this will reassure members of the public that the pharmacy is taking actions to address any shortcomings. However, it may also be commercially sensitive or linked to an individual that may be identifiable from the content of the action plan. It may suffice to say that an action plan is in place with a specified date for completion. This would then require a re-inspection and potential amendment to the previous rating.

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

No

The inspection outcome should be available on line with unrestricted access. We do not think it should be a mandatory requirement to display this in the pharmacy. Also we have concerns about the wording and nature of the 'standards met/not all met' split and the arbitrary nature of the 'good' and 'excellent' ratings.

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

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

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

We welcome the development of the information hub as it will encourage the sharing of good practice and make information more accessible. It may be useful to link this to the pharmacy pages on NHS Choices as it could be helpful to the public to have all the feedback in one place.

[In the Publishing inspection reports section, we describe the process we will follow when quality assuring and publishing inspection reports.](#)

18. Do you have any comments about the publication process? Please give comments explaining your response.

The publication process should give clear reassurance of a commitment to improve the standards of practice with robust and effective mechanisms in place to address any shortcomings. Any subsequent guidance and corrective direction provided should be non-punitive and engender a supportive culture.

[Overall questions about these proposals](#)

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

Positive impact

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

Both positive and negative impact

The majority of the owner of registered pharmacies are likely to view this positively, although some may have reservations.

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

Both positive and negative

If the pharmacy receives a negative report this could impact negatively on the pharmacy team as they are unable to control the running of the pharmacy and may feel like they are doing a good job.

Overall it depends how this new inspection approach is marketed to the profession and those working in registered pharmacies.

We want to understand whether our proposals may discriminate against or unintentionally disadvantage any individuals or groups sharing any of the protected characteristics in the Equality Act 2010. These characteristics are: Age Disability Gender reassignment Marriage and civil partnership Pregnancy and maternity Race Religion or belief Sex Sexual orientation

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

No impact

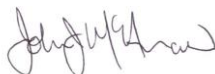
We cannot identify anything in the proposals that would affect anyone from the groups listed.

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

A negative report could impact on some members of staff, including the pharmacist themselves, who are working very hard but are working under the constraints of a corporate body. There should be a greater focus on workplace pressures and the impact that these may have on the staff working in the pharmacy.



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About us

The Royal Pharmaceutical Society (RPS) is the professional body for every pharmacist in Great Britain. We are the only body that represents all sectors and specialisms of pharmacy in Great Britain.

The RPS leads and supports the development of the pharmacy profession to deliver excellence of care and service to patients and the public. This includes the advancement of science,

practice, education and knowledge in pharmacy and the provision of professional standards and guidance to promote and deliver excellence. In addition, it promotes the profession's policies and views to a range of external stakeholders in a number of different forums.

Its functions and services include:

Leadership, representation and advocacy: Ensuring the expertise of the pharmacist is heard by governments, the media and the public.

Professional development, education and support: helping pharmacists deliver excellent care and also to advance their careers through professional advancement, career advice and guidance on good practice.