



Community
Pharmacy
Scotland

**GPhC Consultation on developing the approach to the
regulation of registered Pharmacies**

Prepared by:

Adam Osprey
Policy & Development Pharmacist
adam.osprey@cps.scot

Who are Community Pharmacy Scotland (CPS) & what do they do?

Who we are

We are the organisation which represents community pharmacy contractor owners in almost every aspect of their working lives, and are the voice of these vital healthcare professionals as they deliver pharmaceutical care to the people of Scotland.

We are empowered to represent the owners of Scotland's 1256 community pharmacies and negotiate on their behalf with the Scottish Government. This covers all matters of terms of service and contractors' NHS service activity including remuneration and reimbursement for the provision of NHS pharmaceutical services.

What we do

We work with the Scottish Government on the development of new pharmaceutical care services and ensure that the framework exists to allow the owners of Scotland's community pharmacies to deliver these services.

The Scottish community pharmacy contract puts the care of the individual right at its centre and with its focus on pharmaceutical care and improving clinical outcomes, community pharmacy contractors and their employee pharmacists are playing an increasingly important role in maximising therapeutic outcomes and improving medicine safety. Community pharmacy is at the heart of every community and plays an important part in the drive to ensure that the health professions provide the services and care the people of Scotland require and deserve.



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Introduction

The GPhC are consulting on their proposed developments to the regulation of pharmacy premises, their two main aims being to provide increased assurance to the public that standards are being met and to drive improvement in the profession.

They are proposing six key changes:

1. Introducing new types of inspection

There are proposed to be three types of inspection going forward: Routine, Intelligence-led and Themed.

Routine inspections will continue to be carried out for every pharmacy, though for the next cycle those who have previously been rated as Poor will be inspected first, followed by those rated Satisfactory with actions and so on with those rated Excellent coming last as they are likely to pose the least risk to the public. Factors such as change of ownership may increase a pharmacy premises' priority for inspection. It is expected that it will take longer for inspectors to visit every Pharmacy in the UK under this new model.

Intelligence-led inspections will rely on information received by the GPhC from external sources such as other regulators, healthcare professionals, the public and the media. It is expected that in time, there will emerge patterns from this type of inspection that will shape the routine inspection prioritisation model to further reduce the risk to the public. Themed inspections will be carried out across a number of pharmacy premises, looking at specific issues in more depth than would occur on a routine inspection.

This might include services to care homes or prisons, or where online transactions result in medicines supply – the topics chosen will have been highlighted in routine inspections as areas of particular risk. Other regulators or experts may be invited to take part if appropriate. Themed inspections would result in a single report for each theme, not singling out individual pharmacy premises but highlighting good practice and shortfalls in general to drive improvement, thus reducing risk to the public in these specific practice areas.

2. Unannounced inspections

The GPhC are proposing that all but themed inspections would be unannounced going forward. There is a strong public desire for this to be the case, to better reflect whether standards are being upheld every day. This is in line with the direction of travel for regulation in general and for most independent health and social care services in Scotland, with the exception of Dental and General Practices.

3. Changes to outcomes

The current outcomes of Excellent/Good/Satisfactory/Satisfactory with actions/Poor have not evaluated well with the public or with Pharmacy owners. The proposed change would be to have a simpler binary system of “Met” or “Not met” against each standard, with overall rating being either “All standards met” or “All standards not met”. In order to continue to drive improvement and celebrate success, good and excellent practice will both be annotated as such against each met standard where this has been demonstrated.

Inspectors will continue to use their professional judgement and decision-making framework when deciding whether a standard is met or not, with minor non-compliance unlikely to result in a standard not being met, unless the practice observed poses a risk to the public.

For reference, over 85% of pharmacy premises currently meet all standards on first inspection, with over 99% achieving this after complying with an improvement action plan. The standards for registered premises are not changing as part of this review.

4. Publication

The GPhC intend to publish inspection reports from early 2019 to achieve improved transparency, public assurance and to drive improvement by holding up good practice for the profession to learn from. There are examples of both a “Standards met” and “Standards not all met” version of the proposed summary report (which is anticipated to be most used by the public). There is also an example of a full report, which would also be made available to the public but will most likely be used by pharmacy owners for improvement purposes. Improvement action plans are also proposed to be published. Again, this is in line with the current practice or future plans of most health and social care services.

5. Knowledge Hub and Website

All reports, whether individual or themed, are proposed to be housed on a purpose-built website, which will allow the public and professionals alike the ability to search by a number of terms, including rating, postcode, pharmacy name and so on. A Knowledge Hub will also be set up, which will showcase notable practice found during inspections.

6. Publication process

Before publication on the website, the proposals state that reports would be sent to pharmacy owners to ensure accuracy of content, with a process being developed for where there is disagreement. Every report will be quality assured as they are now, and the pharmacy owner will be notified on publication. The reports are proposed to be published in batches either weekly or monthly.

The full consultation document can be found [here](#), and our response is included below for simplicity.

Section 1: Introducing new types of inspection

In this section, we describe the changes we plan to make to the types of inspections we carry out.

Q1. Do you think the three types of inspection (routine, themed and intelligence-led) will:

Provide more assurance that pharmacies are meeting our standards?

Yes. In particular, the risk-based prioritisation approach to routine inspections will be likely to maximise public confidence in the profession. It is reassuring that each type of inspection will inform the others, so that as time progresses the regulator can move more towards driving improvement in pharmacies consistently meeting/exceeding standards and focussing assurance efforts on the minority of premises where enhanced support in the form of improvement plans is required.

Enable us to be more agile and responsive to risks or changes in pharmacy or healthcare?

No. There is a potential for the responsiveness of the proposed approach to be lost when it comes to the real-world implementation of the intelligence-led inspections. Whilst the intent behind these is sound, we would call for a robust and transparent process and decision framework for appraising intelligence submitted to the GPhC, with weightings attributed to types and volumes of evidence gathered. Each submission would need to be assessed as to whether it would or would not increase prioritisation for inspection.

The number of public complaints to the GPhC has risen dramatically in recent years, and whilst we deeply value comments, concerns and complaints as learning opportunities, we understand that there are a significant number of complaints each year which are unfounded or pose no risk to the public nor breach any of the standards. For these to lead to inspections would not reflect the best use of inspectors' or pharmacy teams' time and may in fact inhibit the GPhC's ability to focus on improvement and to be agile and responsive to change. Care must also be taken to be clear in the difference between evidence relating to a premises as opposed to a pharmacy professional – the latter should not have any bearing on premises inspection unless there is a concern around the environment that the individual is working in.

Help to drive improvements through identifying and sharing good practice?

Yes. The themed inspections will be particularly useful, as they will present a broad view of best practice in one report. This will make it easier for pharmacy owners to pick out the improvements that are most suitable to be implemented in their own unique business model.

However, as we discuss in our answer to questions 3, 4 and 5, there is a risk that having no announced routine inspections will hamper the pharmacy team's ability to demonstrate how they go beyond the standards expected and any innovative practice that they are involved with.

Q2. Do you have any other comments about the types of inspection?

No.

Section 2: Unannounced inspections

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

Q3. 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?

No. The dual aims of public assurance and driving improvement are closely intertwined and reliant on one another: to be trusted, the profession must not only show that it is meeting the expected standards consistently but is also adapting its practice to ensure that patients remain at the centre of what we do in a rapidly changing health and social care landscape. By moving to purely unannounced routine visits, the regulator can confidently demonstrate the former, but by removing the notice period for the vast majority of inspections it removes pharmacy teams and owners' opportunity to organise and showcase the full range of their working practices and innovations. If not demonstrated on inspection, the GPhC will in turn not be able to capture or publish examples of where advancements are being made, to the detriment of other registrants, premises and ultimately to the public's view of the profession.

In summary, we do believe that unannounced inspections have their place in providing the public with assurance that the premises standards are upheld at all times, but these must be balanced with a proportion of the routine and intelligence-led visits having a notice period.

Q4. We have identified instances when it may not be possible to have an unannounced inspection. Are there any other instances we need to consider?

Yes.

Q5. Please describe the other instances we should consider.

As discussed, we believe that the unannounced inspections should be interspersed with announced inspections, to enable Pharmacy teams to be able to demonstrate both good practice and innovation so that it is captured in the report and available for others to learn from. This could be done in such a way that public confidence is not affected, for example by adopting a risk-based approach that has fewer announced visits to pharmacy premises that have previously been rated as poor or have had action plans.

Q6. Do you have any other comments on us carrying out unannounced inspections as a general rule?

No.

Section 3: Changes to the outcomes of an inspection

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

Q7. We propose having two possible overall outcomes from an inspection - 'standards met' and 'standards not all met'. Do you think this will make it clear to patients, the public and pharmacy owners that a pharmacy has met, or not met, the standards?

Yes, provided that updated reports are written, quality assured and published as quickly as is reasonably possible following a re-inspection or action plan being completed. It is the experience of our members that the turnaround for reports can be protracted, and this may have an impact upon a pharmacy premises if their efforts to improve are not recognised for an extended period of time.

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

Provide owners, their teams and the GPhC with a way of measuring performance?

Yes. Having these annotations against each standard will enable teams to focus their efforts on areas which need improvements, and to recognise and celebrate success where appropriate.

- **continue to drive improvement?**

Yes. However, instead of a pharmacy owner or team having to read through a number of reports to get an idea of what is currently regarded as good or excellent practice, we suggest that the reports are uploaded in such a way that the search function allows for a user to pull together and export (for example) all the sections rated excellent in the last month, or all findings under a given principle in the last year – not necessarily by pharmacy.

Q9. Do you think that not meeting one standard should result in the pharmacy receiving an overall outcome of ‘standards not all met’?

Yes – but this should be kept under review as the standards evolve.

Q10. 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’?

No.

Q11. Do you have any other comments on the changes we are proposing to the outcomes of an inspection?

No.

Section 4: Publication

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

Q12. Do you think we should publish inspection reports?

Yes.

Q13. Do you think publishing inspection reports will:

Provide greater transparency about the outcome of an inspection?

No, not in the proposed format. Having two documents will be confusing and may obscure detail for those that wish to read into it – we suggest a single interactive document that displays the summary report, but with each section able to be expanded to reveal the full report content. We also believe that although the summary report will be clear as to whether standards have been met, there is no recognition of whether good or excellent practice was found unless members of the public choose to read the full report, and it is not expected that they will do this.

With regards to language, this must be as clear as possible for the public to understand, and free of any jargon which may get in the way of painting an accurate picture of the pharmacy's performance. In our experience, the style in which reports are written can vary and may not always be accessible to members of the public.

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?

Yes, provided that the user interface supports the interrogation of all published reports at once so that pharmacy owners can easily identify exemplary practice without having to wade through individual reports.

Q14. Do you have any suggestions about the intended format and content of the summary and detailed inspection reports?

Yes – please see our answer to Q13.

Q15. Do you think we should publish improvement action plans?

Yes. Much like the inspection reports, the pharmacy owner must have a say on the content and in particular the timelines to be followed by the pharmacy team to ensure that the plan is achievable. The action plan should also be absolutely clear on the timelines of the GPhC's actions, as if the action plan calls for a given improvement to be implemented by January but the re-inspection and subsequent report publication take until April and this is not explained, members of the public looking at an action plan in February may call into question whether the pharmacy has made any efforts to meet the standards.

Section 6: Publication process

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

Q18. Do you have any comments about the publication process?

Yes. The reports should be published weekly so that the most up to date information is available to the public. Given that the writing and quality assurance of reports can already take some time, adding up to a month onto this for publication is not acceptable – particularly where an improvement action plan is in place and has been completed.

The process to be followed when there is a disagreement on the content of a report should be consulted upon before finalised – whilst it may not be practical to have a full public consultation, bodies who represent pharmacy owners should be involved in any discussions.

Section 7: Impact of the proposals

Q19. What kind of impact do you think the proposals will have on people using pharmacy services?

We believe that for the most part, trust in the pharmacy profession will increase. That so few pharmacies do not meet all standards on first inspection speaks of the importance that pharmacy teams place on their professionalism and duty to patients, and should be publicised.

We are keen that the GPhC regularly measure public awareness of and trust in the profession, such that the impact of measures such as making dramatic changes to inspections can be properly evaluated. This will also make clearer the path to future developments in pharmacy regulation.

We believe that having unannounced inspections will demonstrate that standards are upheld at all times, but must caution that we expect the opportunity to fully demonstrate good and excellent practice will be inhibited unless there are also announced visits carried out.

Q20. What kind of impact do you think the proposals will have on the owners of registered pharmacies?

Mostly positive. The vast majority of pharmacies meet all standards on their first inspection, with almost all meeting all standards after following an improvement action plan. Public recognition of the high standards found will reinforce the image of the pharmacy as a professional healthcare environment. The ability to use the knowledge hub to identify exemplary practice will drive improvements in the profession and will make service planning and change management within organisations easier if there is evidence of similar work existing elsewhere in the country.

However, having all routine and intelligence-led inspections unannounced will impair pharmacy owners' abilities to demonstrate their organisation's breadth and depth of service provision.

Q21. What kind of impact do you think the proposals will have on the pharmacy team?

Mostly positive. The proposed layout of the reports should better familiarise pharmacy teams with the standards and how they relate to their day-to-day practice. Open accessibility to the content of inspection reports will also allow whole-team involvement in planning improvements to service provision.

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 or; Sexual orientation.

Q22. 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.

Q23. Do you think there will be any other impact of our proposals which you have not already mentioned?

No.