



Response

General Pharmaceutical Council

Consultation on developing the approach to regulating registered pharmacies

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For enquiries regarding this response please contact office@thecca.org.uk

Company Chemists' Association Ltd

4th Floor, Euston House
24 Eversholt Street
London
NW1 1AD

About the Company Chemists' Association (CCA)

Established in 1898, the CCA is the trade association for large pharmacy operators in England, Scotland and Wales. Our membership includes ASDA, Boots, LloydsPharmacy, Morrisons, Rowlands Pharmacy, Superdrug, Tesco, and Well, who between them own and operate over 6,000 pharmacies, which represents nearly half the market. Our members deliver a broad range of healthcare and wellbeing services, from a variety of locations and settings, as well as dispensing almost 500 million NHS prescription items every year.

The CCA represents the interests of its members and brings together their unique skills, knowledge and scale for the benefit of community pharmacy, the NHS, patients and the public. Our vision is that everyone, everywhere, can benefit from world class healthcare and wellbeing services provided by their community pharmacy.

Response

The CCA welcomes the opportunity to respond to this consultation. We have regularly engaged with the General Pharmaceutical Council (GPhC) inspections directorate throughout the implementation of the new premises standards and inspections process. Our members have also worked with their Strategic Relationship Managers to address individual concerns with the inspection process or with individual inspections/reports/inspectors. We are pleased to see that some of the issues we have raised during this period of engagement have been considered further in this consultation.

We agree that a 'one size fits all' approach to regulating and inspecting pharmacies will not always work and we support moves towards a more flexible, agile and responsive approach from the regulator, especially as the delivery of pharmacy services evolves.

It is vital that the inspection, rating and reporting system is fair and fit for purpose. In this context, we have provided comments in response to the specific consultation questions highlighting a few areas which we feel the GPhC needs to consider further. The most significant area of concern for our members relates to the proposals to move towards a binary ('Standards Met / Not Met') rating system. Our members feel that a binary rating system could impact adversely upon the morale of hard-working colleagues whose pharmacies have previously been rated overall as 'Good'. The new system does not feel aspirational or progressive in this regard.

Consultation questions

Section 1: Introducing new types of inspection

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

- provide more assurance that pharmacies are meeting our standards?

YES / NO / **DON'T KNOW**

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

YES / NO / **DON'T KNOW**

- help to drive improvements through identifying and sharing good practice?

YES / NO / DON'T KNOW

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

We are supportive of these changes in principle, but we are concerned that 'intelligence-led' visits could follow vexatious rather than evidence-led 'concerns' being highlighted to the GPhC. We feel the GPhC must be proportionate and pragmatic in its approach to regulation based upon 'intelligence' and we feel there need to be clear criteria and thresholds for what type(s) of intelligence may trigger an inspection visit. Conflicts of interest must also be considered.

We do not support the use of the term 'themed inspection', as these visits are not full inspections and a specific inspection report for that pharmacy will not be produced. 'Themed reviews' may be more appropriate. We feel these reviews must be open and flexible enough to result in a true learning experience for those involved and the rest of the sector.

Section 2: Unannounced inspections

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

YES / NO / DON'T KNOW

Please give comments explaining your responses

We recognise that the GPhC has always indicated its direction of travel towards publication of inspection reports and we are comfortable with this in principle. We welcome transparency but we believe that further work is needed to determine what the publications aimed first and foremost at patients and the public should encompass (see answers within section 4).

We strongly agree that the presence of an inspector must **not** increase risks to patients and we would therefore like to be assured that if any inspector visits a pharmacy which is very busy e.g. due to team member sickness, that they return for the inspection on a different day. As stated in the consultation document, taking part in an inspection requires team members to step away from providing services to patients for short periods and an inspector should leave if they feel that by continuing the inspection they are disrupting the patient journey and putting safety at risk. If the pharmacy team flag any crisis-type situations to the inspector, the inspector should always consider and respect the professional opinion and judgement of the Responsible Pharmacist accordingly. The inspector should always inform, and potentially consult with, the Superintendent Pharmacist in these instances.

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

YES / NO / DON'T KNOW

5. Please describe the other instances we should consider

We believe that inspectors should not be able to carry out an unannounced inspection whilst another external audit or review is taking place (e.g. a contract monitoring, Food Standards Agency or Health Safety Executive visit). Pharmacies located within airports or other restricted areas (such as distance-selling facilities on industrial estates) may also be less accessible for unannounced inspection visits.

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

We believe that in some instances it would be useful for the GPhC to conduct an announced inspection, for example when a pharmacy is being re-inspected to show that it has met all the conditions set out in an improvement action plan. This would allow for the pharmacy owner to ensure all relevant individuals are present for the discussion with the GPhC inspector (including a member of the Superintendent Pharmacist's team or a field/area manager where relevant).

Announced inspections may also be useful where innovative processes or technology are under development so that relevant process owners or experts can be present on the day to answer questions raised by the GPhC inspector. Unannounced inspections would be possible, but probably less helpful or informative, in such circumstances.

Section 3: Changes to the outcomes of an inspection

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

YES / **NO** / DON'T KNOW

Please give comments explaining your responses

We understand that the GPhC inspection model is designed to drive improvement rather than solely provide assurance to the public. We absolutely welcome this intention; however, our members feel strongly that retaining four overall inspection ratings/outcomes is more likely to drive improvement across the sector than moving to a binary system.

Our members feel that the binary rating system ('Standards Met/Not Met') could impact adversely upon the morale of hard-working colleagues whose pharmacies had previously been rated overall as 'Good'. The new system does not feel aspirational or progressive in this regard.

We believe pharmacy teams should aspire to achieve overall 'Good' or 'Excellent' ratings, not simply 'Standards met'. Our members have found the current system to be helpful in driving performance to meet and exceed the GPhC standards. We believe that a simple 'met/not all met' division works against this and undermines the aims we share with GPhC for continuous improvement.

We believe that, if every standard is met and supported by demonstrable evidence with no infringements, then a pharmacy should be awarded a 'Good' rating. In turn this would then mean that the pharmacies which are providing over and above the standards would be deemed to be better than 'Good' i.e. 'Excellent'. Unfortunately this does not seem to be the approach taken by inspectors to date.

We have previously raised significant concerns over the awarding of a 'Satisfactory' rating without the requirement for an action plan to be completed. We believe that the GPhC inspection ratings should be revised to mirror the Care Quality Commission's rating scale, which is very familiar to the public and to healthcare professionals i.e.

- **Outstanding** - the service is performing exceptionally well
- **Good** – the service is performing well and meeting expectations
- **Requires improvement** – the service is not performing as well as it should and the regulator has told the service how it must improve

- **Inadequate** – the service is performing poorly and the regulator has taken action against the person or organisation that runs it
- **No rating/under appeal/rating suspended** – the service rating is under appeal from the provider

Overall, we feel a binary inspection model could have a significant negative impact on public confidence in pharmacy. From the point of view of patients and the public, it fails to differentiate clearly between those pharmacies that are well below the expected standards (and which are under pressure to make improvements and/or which face sanctions) and those which have had only minor transgressions.

Given the current proportion of 'Satisfactory' ratings awarded, we are concerned about the public and government reaction to an inspection process that finds the majority of pharmacies as potentially not meeting standards to start with, or in time, to all pharmacies being rated as equal (i.e. 'Standards met').

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

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

YES / **NO** / DON'T KNOW

- **continue to drive improvement?**

YES / **NO** / DON'T KNOW

Please give comments explaining your responses

We are supportive of the use of ratings at principle level, but we believe that an overall inspection rating/outcome using a four-scale approach is also needed to drive system-wide improvement, rather than using this scale at principle level only.

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

YES / **NO** / DON'T KNOW

Please give comments explaining your response

We have significant concerns regarding the proposal that not meeting one out of any of the 26 standards would result in an overall indicative judgment of 'Standards not all met'. This fails to distinguish between those pharmacies that may require major improvements in practice or premises and those which have had minor/temporary setbacks.

Whether or not a pharmacy meets each individual standard can be subjective and this change will coincide with the introduction of several other significant changes (e.g. unannounced visits, publication of inspection reports). Given the proportion of pharmacies receiving 'Satisfactory' ratings to date, we feel this approach could result in a very high proportion of pharmacies receiving an overall outcome of 'Standards not all met' which is very concerning as it will have a negative impact on public confidence in pharmacy.

Impact on service availability/commissioning

Inspections can have a considerable impact on patients' access to valued services in the community, as commissioners are increasingly looking to only award contracts for local services

to those providers that are rated highly. We are concerned that the public perception could be one that only 'Good' pharmacies are good enough to provide commissioned services. This issue could be further exacerbated if the proposed binary rating system and failure at standard level is introduced. A pharmacy not meeting one standard does not automatically mean that pharmacy is unsafe and therefore not a suitable place for a patient to access their medicines or other services from.

We have particular concerns that a failure at standard-level could affect service commissioning for several years i.e. until the pharmacy is re-inspected, especially if the pharmacy has only not met one standard, as those deemed higher risk will be re-inspected first. Some improvement action plans understandably take longer to implement than others (e.g. seeking permission to install a wheelchair ramp or re-fitting a consultation room that is deemed by the inspector to be too small).

We feel that deeming a failure at principle level (i.e. the failure of the *majority* of standards within one principle) would be a more proportionate approach to awarding a pharmacy the 'standards not all met' outcome (or requires improvement/inadequate if the CQC approach is to be mirrored).

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'?

Yes. As outlined above, we feel that the terminology used by the CQC (and OFSTED) is more familiar to patients, easier to understand, aspirational for pharmacy teams and likely to drive improvement across the sector. Our members have seen first-hand how the awarding of a 'good' inspection rating using the current system can increase morale and drive improvements in service delivery, especially in areas where pharmacies are located near to each other. In the same way, they have seen the negative impact on their pharmacy teams of a 'Satisfactory' rating being awarded without any detailed recommendations for improvement.

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

Overall, we feel a binary inspection model will result in a very skewed picture of the pharmacy sector for the public which could be easily misinterpreted. We are concerned about the public and government reaction to an inspection process that finds the majority of pharmacies as potentially not meeting standards to start with, or in time, to all pharmacies being rated as equal (i.e. standards met).

Inconsistencies

We still have strong concerns over the current lack of equity with regards to the ratings awarded during GPhC inspections and the information provided on the rationale for any particular rating. We recognise that there will always be a professional judgement call made by inspectors, but as evidenced in the data submissions we have made to the GPhC over the last few years, there are still clear trends in grading patterns characteristic of individual inspectors.

Some inspectors appear more likely to exhibit trends of awarding pharmacies with a 'Satisfactory' rating in the current system without providing action plans or suggestions for improvement. We gathered data on this issue in 2017 and it showed that there was still a very high proportion of pharmacies (55% of the 1489 inspections we had data for) which were not receiving further instructions when awarded a 'Satisfactory' rating. Four inspectors in particular were found to award between 82-90% of the pharmacies they inspected with a 'Satisfactory' rating without an action plan or suggestions for improvement.

There are various things that can affect the rating patterns of different inspectors, including their familiarity with the role and inspection framework, as well as the area in which they inspect. However, CCA members feel that many inspection outcomes are still not aligning with company expectations. Variations in inspection outcomes at notionally similar pharmacies undermines confidence in the process among pharmacy professionals and could be confusing for patients and the public. We would like the GPhC to make clear how variations between inspectors and across regions will be addressed through improved training and more transparent quality assurance processes.

Section 4: Publication

12. Do you think we should publish inspection reports?

YES / NO / DON'T KNOW

Please give comments explaining your response

We are fundamentally supportive of the principle of transparency as a mechanism for quality improvement and we agree that in this context, and where there is now publication of the inspection reports for other NHS-funded and operated organisations, the outcomes from pharmacy premises inspections should be made available to the public.

However, in order to have the desired impact on improving patient confidence, choice and outcomes, it is vital that the inspection, rating and reporting system itself is fair and fit for purpose. We do not believe that the proposed binary scale will have the desired outcomes in this regard. We feel the inspection rating scale needs to be considered further. The current system, and the system proposed in this consultation document, do not align with those used by other regulators such as the CQC or OFSTED which are already well-embedded and well understood. Reporting findings that could be spurious due to the inspection approach, or reporting them in a way that does not give a fair and reasonable account of the standards in place within a pharmacy, is not in the interests of patients or the public, or of the health system.

According to our most recent review of inspections data across CCA members in 2017, over 65% of pharmacies we had data for were being awarded 'Satisfactory' inspection ratings, with 80% of these 'Satisfactory' pharmacies receiving no action plan or suggestions for improvement. This does not reflect a normal distribution pattern and we believe this does not reflect accurately the quality of our members' pharmacies (as 'Satisfactory' falls within the bottom half of the scale). We do not believe that publication of ratings as achieved under the current system will promote public confidence in the capability and competence of pharmacy teams or facilitate informed patient choice. We also do not believe the proposed binary rating scale will improve this.

In order to fully support proposals for publication of inspection reports, we need assurances that the GPhC will work further with the CCA, our members and other relevant stakeholders, to ensure the inspection reports and reporting process meet the needs of the public and of the health and care system. This means ensuring the system has the confidence and acceptance of pharmacy owners and pharmacists. One particular issue that we are concerned about is the potential availability of reports which do not reflect the current status of a pharmacy. For example, if a pharmacy has taken immediate remedial action after receiving a 'Poor' (or inadequate) grading so that the inspection outcome should be updated, rather than remaining available to the public with an inaccurate rating until the next full GPhC inspection.

13. Do you think publishing inspection reports will:

- **provide greater transparency about the outcome of an inspection?**

YES / NO / DON'T KNOW

- **provide assurance to users of pharmacy services that pharmacies have met the standards?**

YES / NO / DON'T KNOW

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

YES / NO / **DON'T KNOW**

Please give comments explaining your response

We are fundamentally supportive of the proposed approach; however, we feel that further work is still required on ensuring that all inspection reports are factually accurate and do not contain any information which is sensitive to a pharmacy team member or the business. We feel that full publication of the improvement plans in particular could put our pharmacy teams at risk.

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

We are content with the format proposed, though our comments regarding the proposed inspection outcome labels withstand.

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

YES / NO / DON'T KNOW

Please give comments explaining your response

We are fundamentally supportive of the proposals to publish improvement plans, as we think it is valuable for members of the public to understand why a pharmacy has received the inspection outcome it has, what it is doing to address this, and to consider whether this affects their decision to access services from that pharmacy. However, we feel strongly that pharmacy owners, Superintendent Pharmacists and the pharmacy team involved in any inspection must have ample time to determine whether the information contained within this report is accurate and appropriate.

Improvement plans must be fair, consistently applied and proportionate. In some instances, changes to pharmacy premises (e.g. requiring a complete re-fit) could force a pharmacy to become loss-making and unviable, potentially leading to a closure. In these circumstances, the overall risks to patients are often increased rather than decreased, especially if these pharmacies are located in areas with few or no alternative pharmacies. These issues should be carefully taken into consideration as the GPhC makes moves towards publication of reports.

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

YES / **NO** / DON'T KNOW

Please give comments explaining your response

We believe this should remain optional. Until the new inspection approach and publication of reports is well embedded, and every pharmacy has been inspected under the new rating model, it does not seem appropriate (or clear for patients) for those pharmacies which have been inspected to display their inspection outcome in the pharmacy.

Section 5: The website and knowledge hub

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

- **make information easily accessible?**
YES / NO / **DON'T KNOW**
- **encourage the sharing of knowledge within the pharmacy sector?**
YES / NO / **DON'T KNOW**
- **enable learning from examples of standards not being met, and of good and excellent practice?**
YES / NO / **DON'T KNOW**
- **drive improvements within pharmacy?**
YES / NO / **DON'T KNOW**

Please give comments explaining your response

Whilst we are thoroughly supportive of the principles behind establishing a knowledge hub to share best practice, it is difficult to comment on whether this Hub will in turn enable learning and drive improvement until it is clearer how the platform will actually work. The system will only support improvement if it is easily accessible and usable for all pharmacy teams, Superintendent Pharmacists and pharmacy owners. We would gladly work with the GPhC to define what a genuinely useful hub which is easy to search and navigate looks like.

Section 6: Publication process

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

Accuracy check

The proposed publication process stipulates that the inspection reports will be sent to the 'pharmacy owner' for an accuracy check. We would suggest that reports should be sent to the Superintendent Pharmacist as well as the pharmacy owner.

Appeals process

We wholeheartedly welcome the development of a formalised process for reviewing the overall outcome of an inspection if a pharmacy owner challenges the decision-making. We feel if inspection reports are to be published, a formalised and clear appeals process for pharmacy owners must be available, especially as other regulators have embedded these processes for the providers which they regulate. The process should be independent and the publication of an inspection outcome/report should be suspended until the appeal outcome is known. We welcome further clarity on what this process is going to look like and would like to work with the GPhC in agreeing a proportionate approach for all parties.

Improvement action plan completion

The proposed publication process states that: "once the inspector is satisfied that the improvement action plan has been completed, that the pharmacy is meeting the standards and that the improvements are being sustained, the GPhC would then publish on its website an updated overall

outcome and report showing that the pharmacy has met all the standards". We welcome this change, but we are unclear as to whether a re-inspection is required prior to the change in overall outcome, and therefore what the timescales are for the updated overall outcome to be made available.

We feel it is particularly important that changes in overall outcome are made rapidly for pharmacies which have completed their improvement plans, especially given the risk-based approach that the GPhC will be using to determine when a re-inspection will be carried out. As, in this context, those pharmacies which are deemed to have only not met one or two standards will not be re-inspected for a longer period of time. This could impact service commissioning, availability of patient care and public confidence, even though the pharmacy has taken the necessary steps to improve. We would suggest that sufficient evidence that a pharmacy has successfully completed its improvement action plan can be supplied directly to the GPhC (e.g. via a Strategic Relationship Manager) separate to a re-inspection, in particular for any pharmacies which have only not met 1-2 standards.

Section 7: Impact of the proposals

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

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

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

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

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

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

We believe that the impacts will be negative due to the risks we have highlighted in our response relating to the unintended consequences of the binary outcomes model (i.e. potentially limiting service availability for patients and driving down pharmacy teams' morale). However, we feel the proposals would generally have a *positive* impact on these groups if the comments we have provided regarding mirroring the CQC/OFSTED approach to inspection outcome labels are taken on board and reflected in the final model. We feel this will help to drive improvement.

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?

YES / **NO** / DON'T KNOW