Latest data on GPhC pharmacy premises inspections

The primary duty of all healthcare regulators is to protect patients. In terms of pharmacy, the PDA believes this overarching duty to protect the public can only be truly effective if pharmacies and those that own or manage them are appropriately regulated.

The General Pharmaceutical Council (GPhC) has a statutory duty to set standards for pharmacy premises. Government has also given the GPhC statutory powers to inspect pharmacy premises and to publish these inspection reports which it has been doing since 1st April 2019.

The PDA has long standing concerns around the effectiveness and impact of GPhC inspections, and those concerns have increased following the most recent analysis.

The GPhC announced a reduction in the number of “routine” inspections beginning in 2022¹ (the 2021 data is severely impacted by the Covid-19 lockdown and is not representative) and the table below shows the impact of this policy.

<table>
<thead>
<tr>
<th>Pharmacy Inspection_Data (From Annual Reports for y/e 31st March)</th>
<th>Number of registered Pharmacy Premises</th>
<th>Routine Pharmacy Inspections</th>
<th>Covid-19 Support calls and visits</th>
<th>Vaccination site visits carried out</th>
<th>Assurance Calls (2023 onwards)</th>
<th>Assurance Visits (2023 onwards)</th>
<th>Totals</th>
<th>Action Plans agreed with pharmacies</th>
<th>Enforcement Notice - Improvement</th>
<th>Enforcement Notice - Conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2024 *</td>
<td>13,311</td>
<td>950</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>140</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2023</td>
<td>13,805</td>
<td>878</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1,205</td>
<td>147</td>
<td>2</td>
<td>15</td>
</tr>
<tr>
<td>2022</td>
<td>13,844</td>
<td>639</td>
<td>750</td>
<td>861</td>
<td></td>
<td></td>
<td>2,250</td>
<td>121</td>
<td>5</td>
<td>22</td>
</tr>
<tr>
<td>2021</td>
<td>13,977</td>
<td>276</td>
<td>4,140</td>
<td></td>
<td></td>
<td></td>
<td>4,416</td>
<td>53</td>
<td>41</td>
<td>5</td>
</tr>
<tr>
<td>2020</td>
<td>14,181</td>
<td>2,892</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2,892</td>
<td>430</td>
<td>6</td>
<td>20</td>
</tr>
<tr>
<td>2019</td>
<td>14,314</td>
<td>3,667</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3,667</td>
<td>520</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* 2024 Annual Report not published as at 01/05/2024 - the 2024 data estimated from other GPhC published data.

To give this context, at the current rate of inspections a pharmacy premises has a probability of having a ‘routine’ inspection once every 15-17 years.

Pharmacy premises are becoming busier and providing ever more clinical services, so risks to patient safety will clearly increase.

¹ Different types of inspections
https://www.pharmacyregulation.org/inspections/different-types-inspections
We can already see significant increase in the number of concerns reported to the GPhC. It is not unreasonable to attribute part of that increase to a root cause which is likely to be related to the standards of the pharmacy premises and the actions of the pharmacy owner (for example by not providing adequate levels of support staff).

<table>
<thead>
<tr>
<th>From Annual Report -- to March of each year</th>
</tr>
</thead>
<tbody>
<tr>
<td>GPhC Launched 27 September 2010</td>
</tr>
<tr>
<td>New GPhC Pharmacy Inspection Process from 1/4/2019</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Annual Concerns Received</th>
<th>2019</th>
<th>2020</th>
<th>2021</th>
<th>2022</th>
<th>2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concerns Received</td>
<td>2,674</td>
<td>2,985</td>
<td>2,998</td>
<td>3,080</td>
<td>4,178</td>
</tr>
<tr>
<td>Public</td>
<td>1,439</td>
<td>1,627</td>
<td>1,756</td>
<td>1,745</td>
<td>2,888</td>
</tr>
<tr>
<td>Other Professional</td>
<td>360</td>
<td>498</td>
<td>449</td>
<td>606</td>
<td>765</td>
</tr>
<tr>
<td>Inspector or Internal</td>
<td>264</td>
<td>247</td>
<td>121</td>
<td>127</td>
<td>146</td>
</tr>
<tr>
<td>Other (anonymous or category not chosen)</td>
<td>230</td>
<td>228</td>
<td>238</td>
<td>323</td>
<td>71</td>
</tr>
<tr>
<td>Employer</td>
<td>167</td>
<td>219</td>
<td>168</td>
<td>162</td>
<td>233</td>
</tr>
<tr>
<td>Self</td>
<td>138</td>
<td>111</td>
<td>149</td>
<td>42</td>
<td>22</td>
</tr>
<tr>
<td>Police/Other enforcement</td>
<td>76</td>
<td>55</td>
<td>117</td>
<td>75</td>
<td>50</td>
</tr>
<tr>
<td>Totals</td>
<td>2,674</td>
<td>2,985</td>
<td>2,998</td>
<td>3,080</td>
<td>4,175</td>
</tr>
</tbody>
</table>

The GPhC inspection reports are written in a narrative style in five sections which align with the five premises standard principles. The GPhC publishes an inspection framework, the current one is dated April 2019, to explain how a standard would be “met” or deemed “not met”. In addition, it publishes an inspection practice note to cover situations which it describes as “minor non-compliance.”

Whilst the narrative is easy to read there is a lack of consistency in detail and language. For example, many reports generically state: “The pharmacy has enough staff for the services provided.”

The criteria by which a GPhC Inspector decides that a pharmacy has sufficient staffing is unclear. The PDA has long standing concerns around how the GPhC approach staffing levels and how this standard is determined to have been achieved during inspections.

It is notable that Community Pharmacy England (formerly PSNC), the representative body for pharmacy owners in England themselves highlighted significant staff shortages leading to increased workload and recognised not only the impact on

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2 What can patients and the public expect from registered pharmacies? [https://inspections.pharmacyregulation.org/standards](https://inspections.pharmacyregulation.org/standards)

3 The GPhC’s approach to staffing levels [https://www.the-pda.org/the-gphcs-approach-to-staffing-levels/](https://www.the-pda.org/the-gphcs-approach-to-staffing-levels)
patient care but also on staff wellbeing.\(^4\) The GPhC reports are in stark contrast to what pharmacy owners and staff are themselves reporting.

Appropriate regulation is a fundamental structural issue with an impact on patients. If the GPhC cannot adequately ensure standards in pharmacy premises, the PDA believes that alternatives must be considered.

The PDA firmly believes that rather than being regulated by the GPhC, pharmacies should be regulated by the Care Quality Commission in England, the Healthcare Improvement Scotland (HIS) and Health Inspectorate in Wales, like other health settings. This was stated in oral evidence\(^5\) to the Health and Social Care Committee enquiry relating to pharmacy in England on 16 January 2024.

During the session Mark Koziol, PDA Chairman said “.... we have maintained this position for years, that we believe community pharmacy premises should be looked after by the CQC. There is no question about that whatsoever. Not only that, the business owners need to be regulated.”

Later in the session, Mark stated “We have to involve the regulation of people who operate the businesses and non-pharmacists in the healthcare space. We believe the right place is the CQC. We believe that the GPhC should concentrate on the people regulation.”

In response, the GPhC Chief Executive commented that; “community pharmacy premises— legally defined as retail—are registered, regulated and inspected by us. They do not come within the remit of the Care Quality Commission” and we agree with his subsequent comments that on this “there is an entirely sensible debate to be had....” \(^5\)

Indeed, the Professional Standards Authority recently re-confirmed (in its evidence to a Parliamentary Inquiry) its long standing position that all the ten UK healthcare regulators should be merged:

“We have called for them to be merged into one large, multi-professional regulator, to help reduce complexity.” \(^6\)

Considering the most recent analysis of inspections reports undertaken, the PDA will continue to assert the position that the CQC should become the regulator of pharmacy premises.

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\(^4\) PSNC Briefing 009/23: Summary of the results of PSNC’s 2023 - Pharmacy Pressures Survey  

\(^5\) Health and Social Care Committee Oral evidence: Pharmacy, HC 140 - Tuesday 16 January 2024  
https://committees.parliament.uk/oralevidence/14087/pdf/

\(^6\) Written evidence from Professional Standards Authority (PSA) to Industry and Regulators Committee inquiry into UK regulators (UKR0066)  
https://committees.parliament.uk/writtenevidence/126817/pdf/
Appendix One – provides examples from GPhC inspection reports in the past 12 months.

1. Pharmacies Repeatedly Failing to Meet Premises Inspections:

There are several currently registered pharmacies which have repeatedly failed to meet premises standards, with the most recent failure in the past 12 months.

The GPhC process for when a pharmacy fails to meet standards is that an improvement action plan is put into place and the pharmacy has up to 60 days for it to be implemented. The pharmacy self-declares that it has undertaken the improvement action and the GPhC usually undertakes a further inspection six months later. The arrangement allows the owner or pharmacy superintendent to self-declare that they are now meeting standards with no check to validate this from the regulator.

When pharmacies repeatedly fail to meet standards there is an ongoing public risk, but there seems to be no appetite to refer the persons responsible to the pharmacy through any fitness to practice process. The GPhC has powers to refer pharmacy owners to the fitness to practice committee if they are registrants, and it is important that they exercise this duty as it may prevent the proprietors of failing premises from acquiring further pharmacies until the existing problems have been addressed.

The PDA’s review of inspections and pharmacy ownership has revealed that pharmacy owners whose premises have repeatedly failed inspections are not prohibited from acquiring even more pharmacy premises.

2. Pharmacy Inspection Reports Where It Is Unclear How Previously Unmet Standards Have Been Met:

There are reports which seem to indicate that despite issues being identified in an inspection which led to the premises being found not to have met the standards, these issues seem still to be ongoing in subsequent inspection reports which now determine that these standards are now met.

Indeed, the re-inspection report still noted:

“Governance: “The pharmacy had systems in place to identify and manage risks associated with its services but due to the lack of a regular pharmacist and manager, they were not always being followed.”

Staffing: The company provides its team members with resources so they can complete ongoing training. However, team members have not been informed of updates recently or completed any ongoing training.

The team was, however, a few days behind with the workload.

Pharmacy Services: But the pharmacy’s team members are not always identifying people who receive higher-risk medicines or making the
relevant checks. This makes it difficult for them to show that people are provided with the right advice when these medicines are supplied.

Although staff knew the process to take in the event of a drug recall, since the manager had been on leave, team members said that drug alerts had not been checked or actioned. The inspector was told that this was because no one knew how to access this information."

Despite this assessment by the GPhC inspector, standards were reported as being met.

3. Inspection reports which indicate wider structural issues within chains of pharmacies and pose a wider patient safety risk and the premises still meeting GPhC standards.

Most community pharmacies are part of a small, medium and large chains (i.e. more than ten pharmacies), known as “multiples”. These chains have policies that are consistent across all their branches and any underlying issue identified at an inspection from one premises owned by a particular chain will probably be the same across all the other branches.

The PDA often supports members in cases where staffing levels are a concern and in many situations the issue is around untrained staff or occasional staff.

This was noted during one inspection, but the inspection report states that the pharmacy has still met all standards including for staffing.

“After discussing this with the inspector the pharmacist asked the trainee MCA to stop dispensing. The team had been supported by colleagues who usually worked in other areas of the store and had received MCA training. But these team members rarely worked in the pharmacy, so they had limited opportunities to maintain their knowledge and skills. This had sometimes led to errors such as the wrong medication being handed over to a person.”

4. Inspections which deemed the standards for governance and staffing to be met by the GPhC, but where there is a clear ongoing patient safety risk.

The GPhC inspection reports consider five premises standards, governance, staffing, premises, services and equipment.

The following examples focus on governance and staffing. NB. The examples below are just a small sample (and there are many similar examples) within inspection reports where the relevant standard was judged as being met.

Governance Standard

Errors and mistakes occur for multiple reasons in healthcare settings. One of the key components in preventing a repeat of the error (and thus reducing risks to patient safety) is by learning from errors and mistakes.
A considerable number of GPhC premises inspection reports show that dispensing incidents are not recorded, not acted upon and staff have limited access to record or learn from errors.

“However, no near miss incidents had been recorded between May 2023 and September 2023 and there was no evidence of the records being used to identify trends or patterns.”

“Dispensing errors that reached the patient were not routinely reported or the cause analysed. But none of the pharmacy team had access to the internal communications centre so they were unable to complete incident reports.”

“There had been no near misses recorded since the end of January 2023; the pharmacists said there had most probably been near misses since then. The pharmacists described that there had not been a dispensing error for some time, with the last reported error being over 600 days before the inspection.”

**Staffing Standard**

There is universal acceptance that staffing is a significant issue in all healthcare settings. However, the role of the regulator is to protect the public and ensure that providers that provide NHS funded care have enough trained staff to safely deliver these services. The impact on staff, their retention and wellbeing, does not seem to be a concern within these inspection reports.

In the inspection reports reviewed, staff are often quoted as being too busy at work to undertake necessary training and having to do it in their own time, which in itself is an indicator of inadequate staffing, yet all these premises met the staffing standard.

“The team was, however, a few days behind with the workload”

“The pharmacy had a range of standard operating procedures (SOPs) to support its safe and effective running…staffing levels were reduced for the period of the leave which heightened pressure … they explained that this meant they did not always follow the company’s operational guidance that supported its SOPs when completing tasks.”

“Members of the pharmacy team were given time to complete training during working hours, but this was sometimes difficult due to how busy the pharmacy was.”

“On arrival, the RP was a locum pharmacist who worked in the branch two days each week. There were no other trained pharmacy staff present. A member of the store team was working on the medicines counter and had been since approximately April 2023. She had not received any pharmacy training but had read the SOPs.”

“During the inspection, the inspector noted that the only trainee dispenser was required to serve people on the medicines counter and work in the dispensary alongside the pharmacist. This situation risked distractions representing your interests | defending your reputation |
and errors occurring. People were served promptly, but prescriptions were not ready to collect. Staff were preparing them when they arrived and giving appropriate waiting times. The pharmacy was currently around 10 days behind with the workload. Pharmacists were required to complete twenty-five vaccinations every day regardless of the pharmacy’s situation. Staff stated that there were usually queues down to the front door because they were normally busy with walk-in trade. The team also frequently suffered abuse from people using their services. In addition, staffing and the pharmacy’s hours had been cut.”