

Inspection practice note 1: minor non-compliance

Effective from 1 April 2019

1. Introduction

What this policy is about

- 1.1. We have an important role in providing assurance to people that the pharmacy services they and their families use will be safe and effective. We also want to drive continuous improvement in the quality of care that people receive when using pharmacy services.
- 1.2. One of the ways that we act to protect the public and to uphold public confidence in pharmacy is by ensuring that pharmacies meet our standards for registered pharmacies.
- 1.3. This guidance sets out the approach and principles we follow when considering whether standards are met and the criteria to take into account.

What falls outside this guidance

- 1.4. This policy focuses on the general approach to be taken by inspectors when considering compliance with the premises standards in light of all their inspection findings. It cannot substitute for the professional judgement of inspectors in individual cases and the pharmacy context is everything. This document should be read as a general guide to making judgements about compliance with pharmacy standards, alongside other published inspection materials, such as the Inspection Decision Making Framework.

2. Our approach to assessing compliance with standards

- 2.1. Under our revised approach, a pharmacy must meet all the standards for registered pharmacies every day and not just during an inspection, to receive an overall outcome of 'standards met'. If a pharmacy has not met any standard, this would result in a 'standards not all met' rating overall. This is because the standards have been in place for over five years now and patients would expect that if a pharmacy receives a 'standards met' outcome they have met all the standards.
- 2.2. It is likely that in most inspections of pharmacies, inspectors will identify a number of areas for improvement. These may be of a relatively minor nature and not sufficient for a standard to be failed. Nonetheless, they will still be included in the inspection report so that pharmacies can act on them. However, in some circumstances the decision about whether a standard has been failed or not will be less clear cut.

2.3. Inspectors use their professional judgement based on the evidence they collect at the pharmacy to decide whether a standard has been met or not. They also use the inspection decision making framework to help them do this. When making a judgement as to whether a standard has been met, the inspector will consider the impact and scale of the weaknesses or areas for improvement identified. The greater the impact on patient safety, the more likely it is that the standard will not be met. While relatively minor issues are unlikely to result in a standard not being met, there may be a cumulative impact of relatively minor multiple individual shortcomings which could lead to the conclusion that a standard is not met. Again the context of the pharmacy will be a key consideration.

3. Principles that guide our approach to assessing compliance with standards

3.1. The following principles guide our decision-making on assessing compliance with standards.

Proportionality

3.2. Proportionality is about responding appropriately and taking the right action to secure compliance. This will generally involve taking account of the degree of the risk caused by any concerns or weaknesses identified. We take action that we consider to be proportionate in the circumstances of an individual inspection.

3.3. Our reports will include areas for improvement which won't result in standards being failed, as they are not sufficiently serious in terms of the risks to patient safety. We expect pharmacy owners to consider all the findings set out in our report (and not just those set out in any improvement action plan for failed standards) and to take appropriate action to address these. This is an essential strand of our approach to proportionality.

3.4. Similarly, there may be circumstances where, although a legal requirement is not being complied with, the overall evidence is sufficient to support a judgement that the pharmacy meets the relevant standard. The pharmacy context and the scale and nature of the risks to patients will always be our overriding consideration and reports will make it clear to the reader why we have reached our judgement. Again, we would always expect action to be taken to ensure compliance with legal requirements, even where it is not sufficient to fail a standard.

Consistency

3.5. Consistency means taking a similar approach in similar cases to achieve similar outcomes within which a degree of discretion is available. We aim to be consistent in applying our inspection judgement by, as far as possible, dealing with similar cases in a similar manner. However, it is important to note that:

- the facts in one case are rarely replicated exactly in another case. Even though we aim to achieve broad consistency, we will take different decisions in cases where the facts are not the same. The context of the pharmacy will be all important.
- inspection decisions rely on the individual professional judgement of inspectors and each case is evaluated on its own facts and circumstances and the assessed risks.
- we train and support our inspectors and others involved in the decision making processes to promote consistency in our approach and we have a range of oversight and quality

assurance processes. All staff who undertake inspections will be required to follow this guidance.

- we collaborate with other regulators where appropriate, to promote consistent approaches.

Transparency

3.6. Transparency is about helping pharmacy owners to understand what is required of them at the outset and setting out what they may expect from us in return. This means that:

- we are open and transparent about our approach to assessing compliance, consistent with how we carry out our regulatory functions.
- we are clear about what we expect and how we approach cases where registered pharmacies are not meeting our standards.
- we publish relevant information including the factors that we take into account when making decisions and the processes for making representations against our decisions.
- we will also be publishing information about inspections, including inspection reports, we have undertaken, when this is appropriate.
- we will share learning from inspection activity wherever possible, through our knowledge hub on our website, so that it can be used by pharmacy owners and the sector more widely.

Targeting

3.7. We use strategic and operational risk assessment to focus our resources where we believe they are most needed.

3.8. We concentrate on the activities which create the most serious risk, either because the nature of the activity is inherently high risk, or because of a lack of appropriate controls or appropriate response in other less high-risk activities.

3.9. This involves identifying and focusing on those responsible for the risk.

Accountability

3.10. Our inspection activities will be open to public scrutiny. This means that:

- we are accountable to the public and our actions can be judged against the principles and approach in this guidance and other inspection materials
- we will provide additional information outside of the decision-making framework on examples of what constitutes an issue or concern which would not result in a standard not being met
- pharmacy owners have the opportunity to highlight any factual inaccuracies in draft inspection reports
- pharmacy owners can request a review of the overall scored judgement that not all standards are met; and
- pharmacy owners are able to make a complaint about the service they have received via the GPhC's formal complaints procedure

4. Criteria for assessing compliance with standards

- 4.1. There are a number of factors that we consider when deciding whether any shortcomings in relation to individual standards can be considered minor enough that the standard can still be considered met. These factors include, but are not limited to:
- a. The context of the pharmacy
 - b. The level of risk to patients or the public
 - c. The nature and seriousness of the concern(s)
 - d. The impact and scale of the concern(s)
 - e. Whether it is an isolated incident or involves repeated or multiple failures
 - f. Whether it is easily rectified
 - g. The willingness and ability of the pharmacy owner to meet the standards, including any remedial steps already taken
 - h. Any other relevant considerations
- 4.2. In all cases, the context of the pharmacy will be important in making the assessment about individual standards and the standards overall using the above criteria. The greater the impact on patient safety, the more likely it is that a standard will not be met. Relatively minor issues and technicalities are unlikely to result in a standard not being met, as is the case now. For example, minor omissions with records or cluttered storage areas which do not present significant risks. Appendix 1 includes further examples from inspections of the sorts of issues that would not constitute a failure of specific standards.
- 4.3. When making a judgement, inspectors will look across all of the evidence, weighing up all the strengths with all the areas for improvement. While some standards are fairly specific, such as standard 1.5 (Appropriate insurance arrangements), the majority require a more rounded judgement, based upon evidence obtained across the whole inspection, such as standard 1.1 (Risks identified and managed) and 2.4 (A culture of openness, honesty and learning).
- 4.4. The updated inspection decision making framework provides examples of how the standards might be met and examples of inspection findings that could indicate standards are not met. It is not intended as a checklist and not every example will need to be in place for a pharmacy to receive a rating of standards met.

Appendix 1 : Examples of concerns that are insufficient to fail a standard

Risk management and SOPs (Standard 1.1)

Inspectors may come across issues with the standard operating procedures (SOPs) in pharmacies.

Typical concerns could include:

- the absence of a required responsible pharmacist SOP
- version control
- out of date SOPs
- lack of staff signatures confirming they have read and understand SOPs
- responsibilities not clearly defined
- SOPs not fully reflecting current practice

The following is an example for this standard.

While relevant standard operating procedures (SOPs) were in place for the services provided by the pharmacy, some SOPs were past their date of review date by a few months, for example 'receiving a prescription from a customer' and 'professional/clinical assessment of a prescription'. Some roles and responsibilities have not been clearly set out in SOPs (for example, the circumstances in which a member of pharmacy staff who is not a pharmacist may give advice about medicinal products), however staff have a clear understanding of their role and receive appropriate supervision.

Safety and quality reviewed and monitored (Standard 1.2)

Pharmacies are required to have adequate arrangements in place to assess the safety and quality of the services they provide and to take appropriate action when things go wrong or mistakes are made. One of the ways they do this is by recording dispensing errors and near misses to identify the reasons and take remedial action to prevent a recurrence. Pharmacies can often describe the action they have taken following an incident, but this is not always systematically documented to identify trends or wider system issues.

The following is an example for this standard.

Dispensing errors and near misses were recorded on the PMR but, of those viewed, there was no indication of action taken as a result, or formal recording of trends. On questioning staff, it was apparent that recent action had been taken in response to picking errors. For example, different strengths of medication were separated on the dispensary shelves with stickers used to highlight medicines with similar packaging. The pharmacy had also changed wholesaler for one particular drug because the packaging was so similar to another drug. Staff also confirmed that errors and near misses were routinely discussed within the team when they occurred.

Review and monitoring mechanisms for recording and monitoring of near misses and dispensing incidents could be improved but this is not sufficient to fail a standard without any other evidence

suggesting risks to patient safety. The inspection report would set out the areas where improvements are needed.

Record keeping (Standard 1.6)

Pharmacies are required to maintain a wide range of records and inspections will involve reviewing a sample of these to ensure risks are being managed effectively. Inspections often identify gaps in record keeping, and so inspectors have to judge the significance of these on patient safety. Where there are multiple concerns with different records or where the issues are critical it could result in the standard being failed.

The following is an example for this standard.

On looking through the private prescription record book the inspector sees that in the previous few months there are four records which are incomplete, with either the date of the prescription, the prescriber's address or the quantity of medicine left out. The CD register is well maintained with monthly audits of the running balance but headers were missing from the tops of some pages. In general, apart from these exceptions, record keeping including within the pharmacy was up to date and complete.

These findings are relatively minor and are limited in number and so they are unlikely to affect patient safety or patient care. In these circumstances the relevant standard is judged to be met.

Services delivered safely and securely (Standard 4.2)

This standard could cover many of the activities undertaken by a pharmacy and so there is likely to be a broad range of evidence to judge whether it is met. The findings will need to reflect the context of the pharmacy.

The following is a limited example for this standard.

Pharmaceutical stock is subject to quarterly date checks on a rolling basis and the date of the checks is recorded on a calendar. However, the most recent scheduled date for checking had passed several weeks ago. This is reported to be due to short term sickness absences in the team. No out of date stock was found on the shelves and stock with short expiry dates was tagged with different coloured tags. The expiry dates of medication were also checked as part of the dispensing audit process.

Medicines and medical devices, safe, fit for purpose, stored securely, supplied and disposed of safely (Standard 4.3)

This standard covers all aspects of the safety of medicines management in a pharmacy. The example below addresses a specific legal requirement not being met and other steps in place to ensure secure storage of medication.

Schedule 2 and 3 Controlled Drugs were stored within the CD cabinet located in the stockroom at the rear of the premises. Whilst this cabinet does not comply with the Misuse of Drugs legislation, as it is attached to the wall by screws, rather than being bolted to the wall as the legislation describes, it is securely fixed, in a secure location in the pharmacy which is also alarmed. Access to the CD cabinet is managed appropriately, with the key held on the pharmacist while the pharmacy is open and there is a system in place for safe custody of the key overnight.