General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Berkeley Court Pharmacy, 5-7 Melcombe Street, LONDON, NW1 6AE

Pharmacy reference: 1040552

Type of pharmacy: Community

Date of inspection: 10/01/2024

Pharmacy context

This is an independent retail pharmacy located in central London close to Baker Street station. People who visit the pharmacy usually live or work locally, and some of its customers are tourists. The pharmacy dispenses private and NHS prescriptions, and it sells some over the counter medicines and other merchandise. The pharmacist is able to prescribe medicines and provides some private consultations.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; Statutory Enforcement

Follow this link to find out what the inspections possible outcomes mean

Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards not all met	1.1	Standard not met	The pharmacy does not effectively manage risks. It does not have appropriate risk assessments or policies and procedures in place for the services it provides.
		1.6	Standard not met	The pharmacy does not keep accurate and up to date records to show how it supplies and manages medicines safely.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy cannot show that its team members complete appropriate training for their roles.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot show that all prescriptions supplies are safe and legal. And the prescriber cannot demonstrate how he makes decisions, or why he prescribes medicines.
		4.3	Standard not met	The pharmacy does not always store and manage its medicines appropriately to make sure they are properly safeguarded and fit to supply.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy does not effectively manage the risks associated with it services. It does not keep accurate records so it cannot always show it supplies medicines safely. And it does not have up to date policies and procedures explaining how it operates or proper governance arrangements for its pharmacist prescribing service. This means it may not always provide safe and effective services. Pharmacy team members generally understand their responsibilities. And they know how to keep people's private information safe and protect the welfare of vulnerable people.

Inspector's evidence

The pharmacy had recently changed ownership. A copy of the pharmacy's current professional indemnity insurance certificate was displayed. The sole director was the superintendent pharmacist (SI) and he worked as the regular responsible pharmacist (RP). An RP notice was displayed which identified that the SI was the pharmacist on duty. He was not present at the pharmacy at the start of the inspection as he was delivering medication. The dispensing assistant was able to contact him, and she knew she should not sell any Pharmacy medicines, dispense or handout prescriptions while the pharmacist was absent. The SI had not recorded his absence in the RP log, but he completed the record on his return when this was pointed out. The RP log had other information missing as the pharmacist did not always record the time when he ceased his duties. This could make it harder to identify who was responsible for the safe running of the pharmacy at a given point in time.

The pharmacist explained he was using the previous owner's standard operating procedures (SOPs). But the SOPs had not been formally adopted or reviewed to check they reflected the pharmacy's operational activities. And current team members had not signed them to show they had read and understood them which means the team might not always be working effectively.

A complaints procedure was explained on a poster displayed on the counter. The SI couldn't recollect any errors or dispensing incidents since the change of ownership. He suggested that if any errors did occur, the team would discuss and record them, to understand why they had occurred and avoid them being repeated.

The SI was an independent prescriber and confirmed that his indemnity insurance covered this activity. He stated that he occasionally prescribed prescription only medicines (POMs) following a consultation. For example, for a minor ailment or if people had run out of their regular medication. The pharmacy did not have any formal procedures in place for the pharmacist prescribing service. It wasn't clear how it operated, or what the limitations and scope of the prescribing service were. And the pharmacy did not have a documented risk assessment identifying and explaining how risks associated with the prescribing service were managed.

Prescriptions supplies were recorded on the patient medication record system (PMR). The private prescription register was maintained using a facility in the PMR. A sample of private prescriptions register entries were viewed. They often did not accurately record the prescriber's details or the date of the prescription. And the corresponding prescription forms for two records that had been made could not be found. The pharmacy had paper-based controlled drug (CD) registers and running balances were

maintained. Registers were poorly organised, and they hadn't been annotated to indicate the change of ownership which made them harder to audit. Of three CD balances checked, two were found to be accurate but the third identified a discrepancy. This was because a supply of the CD made earlier in the week had not been recorded within the required timeframe. The pharmacy did not have a system to record the receipt and destruction of patient returned CDs. And the pharmacy did not maintain appropriate records when it supplied unlicensed medicines on prescription.

Pharmacy team members kept people's private information safe. Confidential information was generally stored so it wasn't visible to the public. Team members segregated confidential waste which was shredded or removed for safe disposal. They hadn't signed confidentiality agreements, but when questionned, the dispensing assistant understood that people's personal information should be protected. The SI confirmed the pharmacy was registered with the Information Commissioner's office and a leaflet explaining how the pharmacy safeguarded people's personal information was available in the retail area. The pharmacist had completed safeguarding training and he understood what signs to look for and how to escalate concerns. A chaperone policy was displayed on one of the consultation room doors.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy cannot show that its team members complete appropriate training for their roles. And the pharmacy does not have documented staff policies and procedures, so team members may not know what is expected of them or how to raise concerns.

Inspector's evidence

The SI was working with a single dispensing assistant. The pharmacy employed two other part time team members and a part time delivery person. The SI explained that he would usually have a second team member providing support, but no one else was working that day. The pharmacy was relatively quiet, and the workload appeared to be manageable.

The SI was qualified as an independent prescriber specialising in minor ailments, and he confirmed that he had completed training enabling him to administer vaccinations. The dispensing assistant had completed a pharmacy degree but had not finished her training and was not registered as pharmacist. The SI explained one of the other team members was a pharmacy undergraduate. He was unsure what accredited training each team member had completed. He said the delivery person had been given verbal instructions, but they had not completed any training modules. And the pharmacy did not have any staff training records or guidance, such as a staff handbook or whistleblowing policy.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy environment is suitable for the services it provides. It has consultation rooms, so people can receive services and speak to the pharmacist in private. However, some areas of the pharmacy are cluttered and untidy which detracts from the professional image and impacts on the working environment.

Inspector's evidence

The pharmacy was situated in a traditional retail premises. It was arranged over two floors. The retail area, dispensary and consultation rooms were on the ground floor. The retail area was bright and suitably presented. The dispensary consisted of a partitioned area towards the back of the premises with a hatch overlooking the medicines counter. It had a reasonable amount of shelf and bench space.

There were three partitioned consultation rooms accessible from the retail area. One was used by a private hearing clinic on a weekly basis. The second room was for occasional use by a GMC registered doctor to provide skin and aesthetic treatments. It was equipped with a treatment bed and other clinical equipment. The third room was for sole use by the pharmacy team. It was also being used for storage.

Stairs from the retail area led to the basement where there was a staff toilet, additional storage space and several treatment rooms. This area had previously been used by a third-party beauty clinic, but it was no longer operating. The pharmacy was generally clean but some areas, including the dispensary, and pharmacy consultation room were cluttered and untidy.

The pharmacy had a website (https://berkeley-court-pharmacy.business.site/) which provided basic information such as opening hours, the address and contact details. It did not include any more specific information about the pharmacy owner or the superintendent. And it did not advise people how to check the registration of the pharmacy so they could make sure it was genuine.

Principle 4 - Services **Standards not all met**

Summary findings

The superintendent pharmacist sometimes prescribes and supplies prescription medicines for people visiting the pharmacy. But he does not use the necessary documents to authorise the supplies. And he cannot show how he makes decisions, or provide details of the medicines he has prescribed and supplied to people. So the pharmacy cannot demonstate that all prescriptions supplies are safe and legal. In addition, the pharmacy does not always store and manage its medicines safely to make sure they are properly safeguarded and fit to supply.

Inspector's evidence

The pharmacy opened 9am-6pm Monday to Friday. Its main entrance was directly from the street. It had a manual door and level threshold, so it was accessible to most people. There was a second entrance from a small arcade which was used occasionally providing enough team members were working in the pharmacy to monitor the retail area. Various healthcare related leaflets, signs and posters were displayed in the pharmacy. Most of these appeared to have been inherited from the previous owner and they did not always contain the most update information.

The pharmacy dispensed a small number of NHS prescriptions. There was a system for managing repeat prescription requests for regular patients. Dispensed medicines were appropriately labelled. Pharmacy team members sometimes signed ‘dispensed’ and ‘checked’ boxes on pharmacy labels as an audit trail for dispensing. The pharmacy supplied some medicines in multicompartment compliance pack and there were systems in place to make sure these were managed safely. Packaging leaflets were not usually supplied with packs, but the SI agreed to review this to make sure people received them if needed.

The team members were aware of the risks of valproate and isotretinoin for people at-risk and the requirements for a Pregnancy Prevention Programme. The pharmacy rarely supplied valproate products and the team members were reminded of the recent requirement to ensure only original packs were supplied. Isotretinoin was occasionally dispensed. The SI said the prescriber usually indicated on the prescription that the person had been informed of the risks. Assembled prescriptions awaiting collection were stored in the dispensary. A small number were more than six months old, so potentially beyond the validity period or no longer suitable for the patient.

The pharmacy dispensed several private prescriptions each day. Some were received as paper prescriptions and others were sent electronically. The SI could not produce prescriptions for a couple of randomly selected recent private prescription register entries, including a supply made the previous day. And the inaccuracies in the private prescription register meant that he could not determine who had prescribed them or show that the supplies were legal.

The SI explained how he consulted with people visiting the pharmacy and how he sometimes prescribed medication suggesting this happened several times a week. He described how he checked people’s identity when conducting a consultation and how he requested confirmation of existing medications or ongoing health conditions when prescribing. However, he did not record these consultations or issue a legally valid private prescription for the medicines he prescribed. He explained how he entered any

supplies onto the PMR in the usual way when labelling at the time of dispensing. But he could not easily identify the people whom he'd consulted with or show what he'd prescribed and why. He identified a single invoice for a supply of medicines that he had prescribed. This did not constitute a legal prescription and there were no associated consultation notes. And invoices were not routinely produced so these were not a reliable record of what he had prescribed and supplied.

The inaccuracies in the private prescription register meant he could not identify which prescriptions he'd issued and supplied. And he had not considered informing people's usual doctor when relevant when prescribing medicines to ensure effective ongoing care.

The SI occasionally prescribed and administered vaccinations. He produced a document which indicated he had administered a yellow fever vaccine. But there was no associated prescription and batch details of the vaccine had not been recorded. The SI was not able to confirm that the pharmacy was registered as a designated Yellow Fever Centre permitted to undertake this activity.

Team members knew what questions to ask when selling OTC medicines. Pharmacy medicines were stored behind the counter, so people had to request these. The dispensing assistant was aware of which OTC medicines could be abused. She explained how she referred any requests for codeine linctus and Phenergan Elixir to the pharmacist. The SI understood the risk of abuse associated with these medicines and said he was cautious when selling them.

Stock was sourced from several licensed wholesalers. Dispensary shelves were jumbled and disorganised in places, and some medicines were found in random locations. A check of the shelves found a recently expired medicine and an item without a batch number or expiry. There did not appear to be a checking system.
Designated bins were available to segregate patient returned and obsolete medicines prior to collection by an authorised waste contractor. The pharmacy had a medical fridge for storing medicines. The fridge temperature was monitored and recorded to check they remained within a suitable range. But the team members were unsure how to properly read and reset the thermometer, so the associated records were not reliable. CDs were suitably stored, but CD keys were not always under the pharmacist's supervision. Obsolete CDs were segregated in the cabinet. These had accumulated and a destruction was needed. The pharmacy received emailed alerts about defective medicines from the MHRA or through wholesaler communications. However, the pharmacy couldn't show these were systematically checked and actioned.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services. Equipment is suitably maintained.

Inspector's evidence

The pharmacy team had access to the internet and reference materials. There were some approved, clean glass cylinders for measuring liquids. Disposable containers were available for preparing medicines, including compliance packs.

The dispensary and one of the consultation rooms had sinks. Handwashing equipment was available. The CD cabinet was secured and suitable for the amount of stock. Electrical equipment was in working order. Computer systems were password protected and screens faced away from public view. The pharmacist had his own smart card to access NHS data. The NHS smart card for a pharmacist who no longer worked at the pharmacy has been left in one of the terminals. The team agreed to store this securely until it was returned to the owner. A cordless phone enabled conversations to take place in private, if required.

What do the summary findings for each principle mean?

Finding	Meaning
✔ Excellent practice	The pharmacy demonstrates innovation in the way it delivers pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
✔ Good practice	The pharmacy performs well against most of the standards and can demonstrate positive outcomes for patients from the way it delivers pharmacy services.
✔ Standards met	The pharmacy meets all the standards.
Standards not all met	The pharmacy has not met one or more standards.