General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Hallmark Chemists, 245a Bevington Road, Aston,

BIRMINGHAM, West Midlands, B6 6HT

Pharmacy reference: 1037900

Type of pharmacy: Community

Date of inspection: 08/08/2022

Pharmacy context

This community pharmacy is in a residential area of Birmingham. It dispenses NHS prescriptions to local people which it mainly receives from several nearby GP surgeries. The pharmacy has quite a few people who receive instalment supplies for substance misuse treatment. And it has a handful of people in the community who receive medicines in multi-compartment compliance packs to aid compliance. This was a targeted inspection undertaken jointly with a Controlled Drug Liaison Officer (CDLO) following concerns raised about the way the pharmacy was operating.

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 adequately identify and manage the risks associated with providing its services. It has poor stock security and management procedures. The pharmacy regularly orders unusually large volumes of codeine linctus. And the pharmacy cannot properly account for these medicines. This indicates serious systemic weaknesses in the risk management and governance arrangements, which presents a serious risk to patient safety.
		1.6	Standard not met	The pharmacy does not keep its controlled drug records in line with requirements.
2. Staff	Standards not all met	N/A	N/A	N/A
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 is purchasing excessive amounts of codeine linctus without the appropriate safeguards in place to prevent its diversion, misuse and abuse.
		4.3	Standard not met	The pharmacy does not always store its medicines appropriately. And it does not have a robust system to identify and remove date-expired medicines from dispensing stock.
		4.4	Standard not met	The pharmacy does not have a robust system to appropriately deal with safety alerts and recalls.
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 manage the risks linked to certain medicines adequately, particularly with respect to codeine linctus and controlled drugs. It is regularly ordering unusually large volumes of codeine linctus, but it is unclear why these are needed as there is little evidence of it being sold or supplied. As codeine linctus can be abused and cause harm, this risks people's safety. It does not store all medicines that require additional precautions securely. And it does not keep all its records about these medicines up to date. So, its records may not be reliable if they need to be referred to in the future. And the pharmacy may not be able to investigate any anomalies fully or promptly. The pharmacy generally keeps people's private information safe. But it may be missing opportunities to learn from dispensing mistakes as it could not show that it routinely records or reviews these events.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) which covered its services. Team members had signed records which showed that they had read the SOPs that were relevant to their roles and responsibilities. The correct responsible pharmacist (RP) notice was on display in the pharmacy. Team members understood the tasks that they could or could not undertake in the absence of a RP. Team members could explain the procedure they would follow when recording mistakes that were made during the dispensing process. A template for recording mistakes that were made before medicines left the pharmacy (near misses) was available, but no records had been made. A team member said that they had not had any recent dispensing mistakes to report. The RP said that he would notify the superintendent pharmacist (SI) about any dispensing errors. But he was not sure whether the SI reported any patient safety incidents to the National Reporting and Learning Service.

The pharmacy's records about controlled drugs (CDs) were not kept in line with requirements or good practice. And it did not have robust systems to make sure these medicines were always stored securely. Entries in the CD registers were not all made within the required time. The pharmacy kept running balances of CDs but it did not audit running balances regularly. And not all recorded balances reflected the actual stock available or not available in the CD cabinet. A random check of several CDs showed that the quantity of stock did not match the recorded balance. The pharmacy did not keep a register to record CDs that had been returned by people because team members said that this rarely occurred.

The pharmacy had begun keeping more accurate and complete RP records following the recent NHS contract monitoring visit. The RP said that previously they kept electronic records, but he did not quite know how to use the system correctly. And the SI's name and registration number were automatically recorded even though they were not on duty.

The pharmacy had recently registered with the Information Commissioner's office (ICO). A shredder was available in the pharmacy to destroy any confidential waste. Prescriptions awaiting collection were securely stored and the pharmacy's computers were password protected. A current indemnity insurance certificate was on display in the pharmacy.

The RP confirmed that he had completed safeguarding Level 2 training couple of years ago. Team members had recently completed safeguarding training relevant to their roles and responsibilities and they were able to provide their training certificated. The RP was not certain whether the pharmacy had

contact details for local safeguarding organisations. Eneeded.	But he said he could find the details on-line if

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy has enough staff members to manage its current workload adequately and team members work well together. The pharmacy could do more to make sure its team members know how to raise concerns about how the pharmacy is operating so action can be taken to address these promptly.

Inspector's evidence

On the day of the visit, a regular locum pharmacist (RP) and two members of staff were on duty. The two members of staff confirmed that they had completed an accredited dispenser assistant's training with the National Pharmacy Association. The team member's training certificates were not available in the pharmacy.

Members of the pharmacy team appeared to work well together, and they were managing their workload adequately. Members of the pharmacy team said that they would feel comfortable raising any concerns about the pharmacy with the SI. But they were not aware of any whistle-blowing arrangements. And the pharmacy did not have a whistleblowing policy in place. This could mean that concerns about the pharmacy are not be raised or addressed in a timely manner.

Principle 3 - Premises ✓ Standards met

Summary findings

The premises are adequate for the provision of healthcare services, and they are kept secure from unauthorised access when the pharmacy is closed. The pharmacy could do more to ensure its dispensary is kept clutter free.

Inspector's evidence

The pharmacy's retail area was sufficiently spacious, tidy, and free of any obstructions. And it was in an adequate state of repair. The dispensary was untidy and cluttered with paperwork. A sink in the dispensary was equipped with hot and cold running water. But it needed a good clean. There was adequate lighting throughout the premises and the room temperature was suitable for storing medicines. A private signposted consultation room was available for people to have a confidential conversation if needed. The pharmacy could be secured against unauthorised access when it was closed.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not provide all its services safely. It is unable to satisfactorily account for the large quantities of codeine linctus that it orders. And it does not always store its medicines securely, particularly its controlled drugs. The pharmacy obtains its medicines from reputable sources. But it does not store its stock medicines in an organised manner, and some are not kept in their manufacturer's packaging. It does not always keep a record of its medicine's fridge temperatures. This increases the chances of the pharmacy supplying an incorrect medicine or a medicine that is not safe or fit for purpose. However, members of the pharmacy team do try to help people with different needs access the pharmacy's services.

Inspector's evidence

The entrance to the pharmacy was at street level and it was step free. And there was adequate space to accommodate a wheelchair or a push chair. Members of the pharmacy team used their local knowledge to signpost people to other providers if a service required was not offered at the pharmacy. Members of the pharmacy team spoke several other languages such as Urdu and Punjabi and this helped in communicating with people who could not converse in English. A prescription collection and delivery service was offered and a record of all deliveries was kept in the pharmacy to provide an audit trail. People receiving delivered medicines were no longer signing for them, and instead, to help with Covid-19 infection control, the driver annotated the record sheet to indicate that the medicines had been delivered safely.

Baskets were used during the dispensing process to prioritise workload and minimise the risk of prescriptions getting mixed up. On the day of the visit the pharmacy was fairly quiet. An assembled multi-compartment compliance pack was examined. The pack was not labelled with the description of medicine contained in the pack and patient information leaflets were not routinely supplied. This could mean that people or their carers do not have ready access to information to help them take their medicines safely. The RP was aware of the risks involved in supplying valproate medicines to people in the at-risk group. The RP did not think that the pharmacy had any patients in the at-risk group.

Pharmacy-only medicines were stored behind the counter and kept out of reach of the public. The pharmacy obtained its stock medicines from licensed wholesalers and there was enough space in the dispensary to stock medicines safely. But medicines were not all stored in an organised way to minimise the risk of dispensing mistakes from happening. And some medicines were not stored in their original manufacturer's packing. Members of the pharmacy team said that medicines were date checked at regular intervals, but date-checking records were not available at the time of the inspection. A random check of medicines on the shelves found medicines which were well beyond their expiry date stored alongside other stock medicines. These were removed during the inspection. Short-dated medicines had not been marked so that they could be removed at an appropriate time.

Medicines requiring cold storage were kept in a refrigerator. Fridge temperatures were checked during the inspection, and these were within the required range of 2 and 8 degrees Celsius. However, the pharmacy had not recorded fridge temperatures for the month of August. This makes it harder for the pharmacy to show that cold chain medicines were always stored appropriately.

The pharmacy's CDs were not all stored in line with requirements as discussed under Principle 1. Denaturing kits to destroy waste medicines were available in the pharmacy. Waste medicines were stored in designated bins, but these were stored behind the pharmacy counter and were in the public view. This was addressed with the RP during the inspection. The pharmacy was unable to provide any assurances that it had a process to deal with safety alerts and medicines recalls to make sure the medicines it supplied were fit for purpose. Members of the pharmacy team were unable to provide any evidence that recent alerts or recalls had been actioned. They said the SI normally dealt with alerts and recalls.

After the inspection, the GPhC received information that the pharmacy has been obtaining excessive quantities of codeine linctus from the wholesalers. There was no codeine linctus found at the pharmacy during the inspection. During the inspection, the RP said that the pharmacy did not sell any codeine linctus or Phenergan liquid over the counter. On 2 September 2022, the inspector emailed the SI requesting further information about the sale and supply of codeine linctus from the pharmacy. No formal response has been received from the SI to-date.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy generally has the equipment and facilities it needs to provide its services adequately. And it uses its equipment to help protect people's personal information. It could do more to make sure its equipment is cleaned throroughly after use.

Inspector's evidence

Information on the pharmacy's computer terminals was not visible to people visiting the pharmacy and patient medication records were password protected. All electrical equipment appeared to be in good working order. There were several crown-stamped measures available for measuring liquid medicines. These did not appear clean. People's private information was stored securely.

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.