Registered pharmacy inspection report

Pharmacy Name:Shakespears Chemist, 9 Oak Lane, Manningham, BRADFORD, West Yorkshire, BD9 4PU

Pharmacy reference: 1039476

Type of pharmacy: Community

Date of inspection: 26/04/2023

Pharmacy context

The pharmacy is in a parade of shops close to Bradford city centre. Pharmacy team members dispense NHS prescriptions and sell a range of over-the-counter medicines. They provide medicines to people in multi-compartment compliance packs. And they deliver medicines to people's homes.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 doesn't adequately manage all the risks associated with its services. Pharmacy team members don't have access to SOPs that reflect the pharmacy's current practice. And they are unclear about how to provide services safely in certain circumstances.
		1.2	Standard not met	Pharmacy team members do not have robust arrangements to learn from mistakes. They do not record or analyse their mistakes. And they do not routinely make changes to their practices to help make the pharmacy's services safer.
		1.6	Standard not met	The pharmacy does not accurately maintain all of its records. CD register running balances are not effectively audited and private prescription records contain inaccurate information.
		1.8	Standard not met	Pharmacy team members do not demonstrate adequate knowledge to be able to effectively manage concerns about vulnerable people. And they do not have a written procedure to help them do this.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	Several key areas of the pharmacy are dirty and are not properly maintained to ensure the safe provision of the pharmacy's services.
		3.3	Standard not met	The pharmacy has inadequate hygiene and infection control measures in place for the safe provision of its services. And this represents a risk to people's safety.
4. Services, including medicines management	Standards not all met	4.3	Standard not met	The pharmacy does not have adequate processes for managing and storing its medicines. It does not have a robust system for checking expiry dates, and there are out-of-date medicines on the shelves. The pharmacy does not keep all its medicines in the original packs, which increases the risk of errors. And it does not

Principle	Principle finding	Exception standard reference	Notable practice	Why
				always provide people with the necessary written information to help them take their medicines safely.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy doesn't adequately identify and manage all of the risks associated with its services. It does not have written procedures to help pharmacy team members manage these risks. And pharmacy team members are unclear about how to provide services safely in certain circumstances. Team members discuss some of the errors they make in the dispensing process, but they do not record or fully analyse their mistakes. So, they may miss opportunities to learn and make improvements. The pharmacy keeps the records required by law, but not all of its records are accurately maintained. Pharmacy team members suitably manage people's confidentiality. But they do not adequately understand how to protect vulnerable adults and children.

Inspector's evidence

Standard operating procedures (SOPs) to help pharmacy team members manage the risks associated with its services were not available in the pharmacy. The superintendent pharmacist (SI) explained they had taken the SOPs home to review but they had not brought them back to the pharmacy. The SI said the procedures had last been reviewed in December 2021. There was no evidence to confirm that pharmacy team member had read and understood the procedures. One team member could not remember the last time they had read the procedures. Another team member confirmed that they had read some, but not all the SOPs. During the inspection, there were several instances where team members were unsure of the pharmacy's processes or gave conflicting accounts of how things should be done. For example, how to deal with a safeguarding concern about a vulnerable person, how to keep the records required by law, and how to ensure that medicines were labelled properly and safe to use.

The pharmacy had systems for recording errors. The most recent near-miss record was from February 2021. Pharmacy team members recalled errors that had been made since that date, but these had not been recorded. Team members explained how they discussed errors and how they sometimes made changes to help prevent errors happening again. One example had been separating the look-alike and sound-alike medicines amlodipine and amitriptyline on the shelves to help prevent the incorrect medicine being selected. But they admitted that they had not made any recent changes after making mistakes. Old records contained little or no information about why mistakes had happened, or the changes team members had made to prevent them happening again. And the pharmacy team had not analysed the data collected for patterns. The pharmacy did not have any records of dispensing errors it had made, which were errors identified after the person had received their medicines. The SI admitted that errors had been made that had not been recorded. And they could not provide any examples of any learning that had occurred or changes that had been made to make things safer in response to these errors. This meant team members might miss out on opportunities to learn and make improvements to the pharmacy's services.

The pharmacy kept controlled drug (CD) registers as required by law. It kept running balances in some registers, and pharmacy team members audited the running balances against the physical stock quantities each time they made an entry in the register. This meant that registers for CDs that were not used often were not frequently audited. And the pharmacy did not maintain a running balance in its methadone register, so any stock irregularities may be overlooked. The pharmacy kept a register of CDs returned by people for destruction. The pharmacy kept records of private prescriptions electronically. But these records were not always kept accurately. Two examples were found where the prescriber's

information in the record did not match the details on the prescription. And another where the date the prescription had been dispensed did not correspond with the prescription. The pharmacy maintained a responsible pharmacist record. And the pharmacist was displaying their responsible pharmacist notice to people in the retail area.

Pharmacy team members explained that in the event of a concern about a vulnerable adult or child, they would refer their concerns to the pharmacist. But they were unable to clearly explain examples of signs that would raise their concerns. Pharmacy team members had not received any training on safeguarding. The SI could not remember when they had last completed safeguarding training, or provide any evidence of this. There was no documented procedure available in the pharmacy to help team members deal with a safeguarding concern. And team members were unsure about how to report their concerns to the proper agencies.

Pharmacy team members explained feedback was usually collected from people verbally. And any complaints were referred to the pharmacist to handle. The pharmacy had a practice leaflet available for people, which explained how to provide the pharmacy with feedback. The pharmacy had up-to-date professional indemnity insurance in place. The pharmacy kept sensitive information and materials in restricted areas. It shredded confidential waste. Pharmacy team members explained how they protected people's privacy and confidentiality. They gave examples of how they would be mindful of people's privacy when speaking to them about their medicines. And how they were careful not to leave sensitive documents, such as prescriptions, around the retail counter. The pharmacy did not have a documented SOP about confidentiality and data protection available in the pharmacy to help team members achieve this.

Principle 2 - Staffing ✓ Standards met

Summary findings

Pharmacy team members receive the right training for their roles and the services they provide. They complete some ad hoc ongoing training to keep their knowledge up to date. Pharmacy team members feel comfortable discussing ideas and issues.

Inspector's evidence

At the time of the inspection, the pharmacy team members present were the superintendent pharmacist (SI), one dispenser and a trainee who started working at the pharmacy in February 2023. The team managed the workload adequately during the inspection. Pharmacy team members completed training ad hoc by reading various materials and discussing topics with the SI. Pharmacy team members could not give any examples of any training they had completed recently. The pharmacy did not have an appraisal or performance review process for team members. Team members explained they would raise any learning needs informally with the SI, who would teach them or signpost them to appropriate resources.

Pharmacy team members felt comfortable raising professional concerns with the pharmacy's SI and owner. They felt comfortable sharing ideas to improve the pharmacy or raising a concern. And they were confident that their points would be considered. A team member explained how they regularly discussed ways to promote the services to people, for example changing window displays to advertise seasonal products at different times of the year. The pharmacy did not have a whistleblowing policy. Pharmacy team members had some knowledge of organisations outside the pharmacy where they could raise professional concerns, such as the NHS or GPhC. Pharmacy team members communicated with an open working dialogue during the inspection. The pharmacy owner did not ask pharmacy team members to meet any performance related targets.

Principle 3 - Premises Standards not all met

Summary findings

Several key areas of the pharmacy are dirty and poorly maintained. The lack of hygiene and uncleanliness of some key areas represents a risk to people's safety. The pharmacy's retail area is suitably presented and there is a room where people can speak to pharmacy team members privately.

Inspector's evidence

In addition to the ground floor, the pharmacy had a first and second floor. The first floor had a toilet, with a sink which provided hot and cold running water and other facilities for hand washing. The other rooms on the first floor were used for storage.

The stairway that led from the ground floor to the second floor had extensive evidence of bird faeces, both on stair treads and handrails. Team members used the staircase regularly to access the first floor. Pharmacy team members stored totes and boxes on the stairs, which could become contaminated by faeces on the handrails above. The totes contained items they used in their day-to-day pharmacy activities. Although the rooms on the second floor were not used, there was significant evidence of bird faeces and feathers. The superintendent pharmacist (SI) confirmed the pharmacy had experienced issues with pigeons in the upper floors of the pharmacy in September 2022, which suggested that little attempt had been made to clean and remove the debris since the infestation. This presented a significant hygiene and health and safety risk to team members working at the pharmacy and to people using the pharmacy's services. There was evidence of rodent faeces in one of the first-floor storerooms. The SI said they were not aware of any rodent issues in the pharmacy. But there was evidence in the room of attempts being made to control rodents by using a homely remedy. In the area on the ground floor where prescriptions were prepared, pharmacy team members were storing a significant number of dispensing baskets and multi-compartment compliance packs on the floor. This also presented a trip hazard to pharmacy team members. And meant there was a risk of medicines in baskets on the floor being contaminated by rodents.

The pharmacy's retail area was generally tidy and well organised. Other than baskets on the floor in the dispensary, the pharmacy generally kept its benches tidy. The pharmacy had a consultation room where pharmacy team members could have private conversations with people. Heating and lighting were maintained at acceptable levels.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not always store and manage its medicines appropriately. It does not have a robust process for checking the expiry date of medicines. And it does not always keep its medicines in the original packs. So, it may not be able to adequately ensure the safety of its medicines. Pharmacy team members provide some people with advice and information about high-risk medicines. But they do not always routinely provide people with written information to help them take and manage their medicines safely. The pharmacy sources its medicines from reputable suppliers. And people are generally able to access the pharmacy's services.

Inspector's evidence

The pharmacy did not have a documented procedure for checking stock for short-dated and expired medicines. The pharmacy's records of expiry date checking were incomplete and showed that the recorded checks had been completed some time ago. And several areas had not been checked for some time. Team members explained they completed date checking ad hoc whenever they had time. But some of these checks had not been recorded. And team members could not confirm which areas they had checked and which they had not. Some pharmacy team members highlighted medicines that were due to expire by highlighting the shelf where the medicine was kept. Team members confirmed they would remove expiring items during their month of expiry. But this relied on them seeing a sticker on the shelf when they were dispensing. After a search of the shelves, the inspector found five expired medicines with various expiry dates.

Several amber bottles were found on the shelves in the dispensary containing medicines that had been removed from their original packaging. Some of these bottles had labels attached giving information about the medicine and its strength. But none of the labels showed a batch number or expiry date of the medicines in the bottles. And some bottles did not have any labels attached. So, team members could not properly identify the medicines. This meant that there was a risk of these medicines not being removed from stock and supplied to people after they had expired or after they had been recalled by the manufacturer.

The pharmacy received some alerts and recalls from manufacturers. Pharmacy team members relied on being notified of these by telephone by their wholesalers, or by receiving information printed on wholesalers' invoices. The pharmacy did not subscribe to the alert and recall system operated by the Medicines and Healthcare products Regulatory Agency (MHRA). This meant there was a risk it may not receive some alerts. Team members did not record the action they took after they received alerts and recalls.

The pharmacy supplied medicines to people in multi-compartment compliance packs when requested, to help people take their medicines safely. Pharmacy team members ordered prescriptions for these packs several days in advance to give them time to deal with any queries or discrepancies. The pharmacy attached backing sheets to the packs, so people had written instructions of how to take their medicines. But pharmacy team members did not include descriptions of what the medicines looked like, so they could not be identified in the packs. And they did not regularly provide people with patient information leaflets about their medicines. They explained that leaflets were only provided when medicines were newly prescribed. Team members documented any changes to medicines provided in

packs on the person's master record sheet, which was a record of all their medicines and where they were placed in the packs. But the record they made did not provide any details about who had requested the changes and why, to help easily deal with future queries.

The pharmacist counselled people receiving prescriptions for valproate if they were at risk. And they checked if the person was aware of the risks if they became pregnant while taking the medicine. They advised they would also check if they were on a pregnancy prevention programme and taking regular effective contraception. The pharmacist did not record these conversations with people to help with future queries. And the pharmacy did not carry out any regular audits to help identify people at risk. The pharmacy did not have any stock of printed information materials to give to people to help them manage the risks of taking valproate. Other pharmacy team members were not aware of the risks of taking valproate during pregnancy and their responsibilities to help people manage the risks of taking the risks taking taki

The pharmacy had access from the street via a small step. It did not have a ramp available to help people access the premises, such as people who used a wheelchair. Pharmacy team members explained that people usually knocked on the window to attract their attention, and they would go to the door to help them. The pharmacy displayed its opening hours, and it had a leaflet available that explained the services offered and how to contact the pharmacy.

The pharmacy obtained medicines from licensed wholesalers. It had separate areas for labelling, dispensing, and checking prescriptions to help manage the workflow. Pharmacy team members generally kept these areas free from clutter. They used coloured baskets throughout the dispensing process to help prevent prescriptions being mixed up. But they sometimes stored baskets containing prescriptions and medicines on the floor, which was unhygienic and meant they were at risk of being damaged. Pharmacy team members did not always sign the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing. This included when they dispensed medicines in multi-compartment compliance packs. This meant they were unable to maintain an audit trail of the people involved in the dispensing process. And to help the right people learn and reflect when they made mistakes. The pharmacy delivered medicines to people. It recorded the deliveries made. The delivery driver left a card through the letterbox if someone was not at home when they delivered. The card asked people to contact the pharmacy.

Principle 5 - Equipment and facilities Standards met

Summary findings

The pharmacy generally has the necessary equipment available for the services it provides. It manages and uses its equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy mostly had the equipment it needed to provide the services offered. The resources it had available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. The pharmacy had a set of clean, well-maintained measures available for medicines preparation. And it had a separate set of measures for measuring methadone. It had suitable containers available to collect and segregate its confidential waste. It kept its password-protected computer terminals and bags of medicines waiting to be collected in the secure areas of the pharmacy, away from public view.

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.	