General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Boots, Unit A, Westcroft Retail Park, Barnsdale Drive, MILTON KEYNES, Buckinghamshire, MK4 4DD

Pharmacy reference: 1085119

Type of pharmacy: Community

Date of inspection: 11/02/2020

Pharmacy context

This is a community pharmacy in a retail park in Milton Keynes, Buckinghamshire. The pharmacy is open for long hours. It dispenses NHS and private prescriptions. The pharmacy provides a delivery service and can offer Medicines Use Reviews (MURs), the New Medicine Service (NMS) as well as travel vaccinations. And it supplies multi-compartment compliance packs to some people if they find it difficult to take their medicines on time.

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 is not identifying and managing several risks associated with its services. There is evidence that mistakes have happened that have not been handled appropriately. And due to the lack of staff available, the team is not routinely working in line with the pharmacy's standard operating procedures.
		1.2	Standard not met	The pharmacy does not have a robust process in place to manage and learn from incidents. The team is not always making records of incidents or investigating them appropriately and there is limited evidence of remedial activity or lessons being learnt in response.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have enough suitably qualified and skilled staff to provide its services safely and effectively. The current staffing arrangements are insufficient to cope with the workload. Routine tasks are therefore not being completed or undertaken in a timely manner.
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's services are not always being managed and delivered safely or effectively. The team is behind with the workload and the pharmacy cannot show that it is always maintaining effective audit trails about its services.
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 effectively manage risks associated with its services. It has written instructions to help with this. But members of the pharmacy team are not always working in line with them. The team is not always recording its mistakes. The pharmacy has not handled some mistakes appropriately. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. However, team members can protect people's private information. And they understand how to protect the welfare of vulnerable people.

Inspector's evidence

The inspection took place not long after the pharmacy opened in the morning. The pharmacy's workflow was quite chaotic. Most of its workspaces were cluttered with baskets of prescriptions awaiting checks or assembly and several boxes of stock were present that required putting away. This was only partially cleared when the assistant manager arrived to help. The team was behind with the workload and with some of the pharmacy's routine tasks (as described under the various Principles). There were queues of people seen and most people's prescriptions were not ready at the point that they came to collect them. Staff were therefore having to check the pharmacy system and look for prescriptions that had been part-completed in the back section of the dispensary.

One pharmacist was based on the front dispensary bench along with the only full-time dispensing assistant on duty. The latter described providing appropriate waiting times to help reduce the risk of a mistake happening. The near miss log had been placed to one side at the back of the dispensary and there had been no entries made since January 2020. There were also no previous records of near misses and no evidence at the point of inspection, to verify that the near misses had been collectively reviewed. None of the company's 'Patient Safety Reviews' present. In addition, the staff present were unable to recall or provide any details about previous reviews or the improvement actions that may have been taken as a result of these. The store manager later explained that these had been taken home by the regular pharmacist so that the annual patient safety report could be completed. The pharmacy was therefore unable to demonstrate that it actively managed the risks associated with its dispensing services.

The company's practice leaflet was on display and this provided details about the pharmacy's complaints procedure. Pharmacists or members of the management team handled incidents. The store manager explained that when the details had been obtained and an incident report completed, he then investigated the situation to identify ways to minimise the mistake happening again. However, there was evidence that a recent incident involving a hand-out error had not been acknowledged by the pharmacy team. An incident report about this had not been completed. The incorrect medicines supplied had not been retrieved by the pharmacy and the situation had not been handled in line with the pharmacy's documented complaints process. The inspector brought this situation to the attention of the store manager and they were asked to provide a copy of their internal report once they had investigated the situation. A discrepancy involving a controlled drug (see below) was also identified by the inspector during the inspection and this had also not been managed appropriately by the pharmacy.

The pharmacy held a range of documented standard operating procedures (SOPs) to support its services. They were dated from 2018 to 2019. Team members had read and signed the SOPs.

However, their roles and responsibilities had not been defined within the SOPs as the matrix to provide this information was missing. The correct responsible pharmacist (RP) notice was on display and this provided details of the pharmacist in charge of operational activities on the day.

Team members had been trained to safeguard vulnerable people and they described refreshing this mandatory training annually through the company. Staff referred to the RP in the first instance. The pharmacists were trained to level two via the Centre for Pharmacy Postgraduate Education and contact details for the local safeguarding agencies were present. A notice was on display to inform people about how the pharmacy protected their privacy. Confidential waste was segregated and disposed of through the company's procedures and sensitive details on bagged prescriptions awaiting collection could not be seen from the front counter.

The team had completed daily checks to ensure the fridges were operating at appropriate temperatures and records were maintained of the minimum and maximum temperatures. Records of emergency supplies and private prescriptions were maintained in line with the legal requirements. In general, a sample of registers seen for controlled drugs (CDs) had mostly been kept in line with the Regulations. However, loose labels and a small note had been left within one of the CD registers, which was dated from 21 January 2020 to indicate that the balance of this CD was incorrect. This had not been investigated further at the point of inspection and no attempt had been made to try and resolve the discrepancy. There was no incident report about this situation and no details had been reported to the CD Accountable Officer. Information was received following the inspection that this situation had been resolved. There were also issues with the RP record as there were missing entries and the pharmacists had often not entered the time that they had signed out. In addition, there were crossed out and overwritten entries. There were also gaps seen within the company's pharmacy log throughout 2019.

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

Summary findings

The pharmacy does not have enough staff to manage its workload safely. Its current staffing levels means that the team is struggling with the workload. As a result, members of the pharmacy team are under pressure and are unable to keep up to date with routine tasks. This situation is unsafe.

Inspector's evidence

The pharmacy was busy and there was not enough staff present to effectively manage the workload. At the start of the inspection, the pharmacy team consisted of two relief pharmacists and a full-time, trained dispensing assistant. One pharmacist was covering the front walk-in trade with the only dispenser. The RP was situated in the enclosed dispensary behind trying to catch up with the workload here. A part-time medicines counter assistant was covering the counter to sell over-the-counter (OTC) medicines and when she could, came over to help hand-out dispensed prescriptions. The assistant manager who was a trained dispensing assistant arrived shortly into the inspection and worked tirelessly to clear some of the stock and back-log. A third relief pharmacist who was due to cover the late shift along with the store manager arrived towards the latter end of the inspection. The latter was also a trained dispenser.

The store manager explained that he helped in the pharmacy where he could. The pharmacy's area structure had recently changed, and the store manager was unsure whether additional contingency arrangements from other branches would be available. The pharmacy was currently recruiting for a part-time (22.5 hours) dispensing assistant. The team had found it difficult to recruit and some staff had recently left employment without working through their notice period. This had left the pharmacy short of staff. A second regular pharmacist had been employed to start work the following week and according to the store manager, there were hours available for two pharmacists to work staggered shifts during the day to provide cover.

However, the inspector was told that the pharmacy had been struggling with its staffing levels and workload for the past few months. Two pharmacists had been working together for a few weeks at the pharmacy, but this had not helped the team to catch up with the workload as dispensing staff were required.

The pharmacy was not openly offering some of its additional services. They were only provided if people specifically asked for them because the current staffing levels were insufficient to support this. The pharmacists described some formal targets being in place to complete the services. This was described as not being manageable and there was some level of pressure being felt to complete them.

The pharmacy was about a week behind with its prescriptions and people were observed having to wait as their medicines were not ready when they arrived to collect them. The inspector was told by the staff that they had raised concerns about the staffing situation, but the company had no additional staff available in the area to provide cover. Some part-time members of the team had been working over-time and described feeling stressed.

Team members wore name badges. None of their certificates of qualifications obtained were seen. Appropriate questions were asked before medicines were sold over the counter and suitable referrals

to the RP took place. Staff described being kept informed about updates and their progress was monitored through the regular pharmacist. They were provided with resources such as tutor packs and e-Learning modules to keep their knowledge up to date.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises generally provide an appropriate environment for the delivery of healthcare services. The pharmacy is clean.

Inspector's evidence

The pharmacy was clean, bright and appropriately presented. Its premises consisted of a large retail area with a medium-sized dispensary on the right-hand side of the entrance. The dispensary consisted of a front workbench with two areas that were enclosed to the public but as described under Principle 1, most of the walk-in trade was assembled from this space. The enclosed dispensary behind was quite spacious with enough space for storage and for assembling prescriptions. However, most of the pharmacy was quite cluttered initially with no clear bench space available. This situation can increase the risk of errors happening. Pharmacy (P) medicines were stored behind the counter and staff were always within the vicinity. This helped restrict the risk of self-selection. A sign-posted consultation room was available for services and for private conversations. This was kept locked.

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

Summary findings

The pharmacy is not providing its services as safely as it could do. It has been unable to show that it has records in place to safely deliver people's medicines. And overall, it lacks records to verify the safety of its services. This is linked to the lack of staff being available to carry out routine tasks. But the pharmacy does obtain its medicines from reputable sources. And it largely stores as well as manages its stock appropriately.

Inspector's evidence

The pharmacy was open for extended hours. A few seats were available for people waiting for prescriptions. The pharmacy's opening hours were on display and there were plenty of car parking spaces available outside the premises. There were automatic doors at the front of the pharmacy and entry into the pharmacy was from the street. This, coupled with the clear, open space inside the pharmacy, enabled people with wheelchairs to easily enter and use the pharmacy's services. Staff described physically assisting people who were visually impaired. Some members of the team spoke Italian and South Asian languages to help communicate with people whose first language was not English. The team used gestures and spoke clearly to help assist people who were partially deaf.

Multi-compartment compliance packs were supplied after the RP carried out an initial assessment for suitability. The process could not be fully verified as only one part-time member of staff assembled them and other members of the team who were present, were unaware of the process. The pharmacy held individual records for people receiving compliance packs and audit trails had been maintained to verify that some relevant checks were made with prescribers. The inspector was told that on occasion, compliance packs had been made up on the day that they were due to be collected because of the staffing situation.

The pharmacy provided a delivery service. Only one documented record about the delivery of a CD was located during the inspection. The team had not retained or could not find any other information to help verify when or where medicines had been supplied and staff were unable to bring up electronic records. The inspector was also told that the pharmacy had received complaints associated with its delivery service. This was described as due to prescriptions not being received in time.

During the dispensing process, plastic tubs were used to hold prescriptions and items. This helped prevent their inadvertent transfer during the dispensing process. Once dispensed, prescriptions awaiting collection were stored within an alphabetical retrieval system. Staff placed fridge and CD items into clear bags once they were assembled, this helped to identify them more easily when they were handed out.

Staff attached pharmacist information forms (PIFs) to prescriptions during assembly although there were several prescriptions seen in the retrieval system without this. The team usually used laminated cards to highlight relevant information such as CDs, fridge and higher-risk medicines. However, there were prescriptions seen that did not have this information attached for the latter. This meant that relevant checks may not have always been taking place when these medicines were supplied. Some staff were unaware of the risks associated with valproates during pregnancy although the pharmacy did hold educational literature to provide to people at risk, upon supply of these medicines. A dispensing

audit trail from a facility on generated labels was being used to assist in identifying staff involved. However, the company also required its staff to complete details within a quad stamp that was marked on prescriptions; there were several prescriptions seen within the retrieval system that had this information missing. In addition, staff were significantly behind with removing uncollected prescriptions. The pharmacy had consistently not been removing the latter as several prescriptions from October and December 2019 were still present. This included date-expired prescriptions for CDs.

The pharmacy used licensed wholesalers such as Alliance Healthcare and AAH to obtain medicines and medical devices. Staff were unaware about the processes involved for the European Falsified Medicines Directive (FMD). There was no guidance information present for the team and the pharmacy was not yet complying with FMD, which was a legal requirement at the point of inspection.

Medicines were stored in an organised manner. The team date-checked medicines for expiry every week. There was a date-checking schedule in place to verify that this had taken place. Staff used stickers to highlight short-dated medicines. There were no date-expired medicines seen although the occasional poorly labelled container was present. Liquid medicines were marked with the date upon which they were opened. CDs were stored under safe custody and the keys to the cabinet were maintained in a manner that prevented unauthorised access during the day as well as overnight. However, there were gaps within the CD key log which meant that the pharmacy could not fully verify that this process had been carried out. Drug alerts were received through the company system, the team checked for affected stock and acted as necessary. However, there were gaps within the audit trail as other than a few drug alerts from the start of February 2020, the remaining audit trail was from 2019.

Medicines returned for disposal were accepted by staff and stored within designated containers. However, there were no designated containers to store hazardous and cytotoxic medicines or a list available to help the team to identify them. People requiring sharps to be disposed of, were referred to their GP surgery as staff stated they were unsure about where they could be disposed. Returned CDs were brought to the attention of the RP and segregated in the CD cabinet before their destruction.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely. The pharmacy's equipment is kept clean.

Inspector's evidence

The pharmacy was equipped with the facilities and equipment it needed to provide its services. This included current versions of reference sources, counting triangles and a range of clean, standardised conical measures for liquid medicines with designated ones for methadone. The dispensary sink where medicines were reconstituted was clean. There was hot and cold running water available here. The CD cabinets were secured in line with statutory requirements and the medical fridges were operating at the appropriate temperatures. Computer terminals were password protected and positioned in a manner that prevented unauthorised access. There were cordless phones available to help with private or sensitive telephone conversations.

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.