General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Pharmacy, Swan Street, Kingsclere, NEWBURY,

Berkshire, RG20 5PP

Pharmacy reference: 1028949

Type of pharmacy: Community

Date of inspection: 19/07/2019

Pharmacy context

This is a community pharmacy located in the village of Kingsclere, near Newbury in Berkshire. The pharmacy dispenses NHS and private prescriptions. It provides some services such as Medicines Use Reviews (MURs) and the New Medicine Service (NMS). And, it provides multi-compartment compliance aids to help people manage their medicines.

Overall inspection outcome

✓ Standards met

Required Action: None

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 met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✓ Standards met

Summary findings

In general, the pharmacy manages most risks appropriately. It has written instructions to help with this. But team members are not always working in line with them. This could mean that they are unclear on the pharmacy's current processes. When things go wrong, team members deal with mistakes responsibly. But, they don't always record the details or formally review them. This could mean that they miss opportunities to spot patterns or trends. Members of the pharmacy team understand how they can protect the welfare of vulnerable people. And, they know to protect people's personal information. The pharmacy maintains most of its records in accordance with the law. But some details about unlicensed medicines are missing from its records. This means that the team may not have all the information needed if problems or queries arise.

Inspector's evidence

The dispensary was small with limited space to dispense prescriptions (see principle 3). One dispensing assistant assembled multi-compartment compliance aids and the responsible pharmacist predominantly self-checked prescriptions. To maintain accuracy, he explained that one prescription at a time was processed and assembled, he placed generated labels onto packs of medicines in a way where he could easily see all relevant details and when medicines were bagged, relevant details were checked again. if the RP was distracted, he re-started his accuracy-checking procedure.

The pharmacy's team members were not recording their near misses, this was not in accordance with the pharmacy's standard operating procedure (SOP). The RP explained that this was an informal process, mistakes were discussed at the time and medicines with similar names or packaging were identified and separated. This included separating different strengths of atenolol as well as moving latanoprost and latanoprost with timolol away from one another. Elastic bands were placed around the latter to further help to differentiate between the two eye drops.

There was information on display about the pharmacy's complaints procedure and a documented complaints process was available. The RP handled incidents, he explained that relevant details would be checked, the situation rectified, details documented and reported to the National reporting and Learning System (NRLS). The RP stated that no incidents had occurred.

There were a range of documented SOPs present to support the supply of services, but they didn't always match the pharmacy's processes (for example with near misses and for some aspects of the date-checking process). They were prepared in 2015, marked as due for review in 2016. The RP who was also the owner, confirmed that he had reviewed the SOPs in March 2019. Ensuring SOPs were clearly annotated with this information, was discussed during the inspection. Staff had signed to confirm that they had read the SOPs, they understood their roles and responsibilities and knew the activities that were possible in the absence of the RP. The correct RP notice was on display and this provided details of the pharmacist in charge of operational activities.

Team members could identify signs of concern to safeguard vulnerable people, they were trained through the RP and would inform him in the event of a concern. The pharmacist was trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE). However, there was no SOP seen to support the process or relevant local contact details for the safeguarding agencies. The RP thought that

he may have taken this information home with him.

There was information on display to inform people about how their privacy was maintained and there was no confidential material left within public facing areas. Confidential waste was shredded and dispensed prescriptions awaiting collection were stored in a location where sensitive information could not be seen. Staff were trained on the EU General Data Protection Regulation (GDPR).

Records relating to most pharmacy services were compliant with statutory requirements. This included the RP record, private prescriptions, emergency supplies and in general, a sample of registers seen for controlled drugs (CDs). Balances for CDs were checked visually and with each transaction, there was some indication of when this occurred as it was marked in the registers. On randomly selecting two CDs held in the cabinet, their quantities matched balances that were recorded in the corresponding registers. There were however, prescriber and people's details missing from most records of unlicensed medicines and some registers contained incomplete details about the address of wholesalers when CDs were received.

The maximum and minimum temperatures for the fridge were checked every day and records were maintained to verify that appropriate cold storage of medicines occurred. Staff kept a record of CDs that were returned by people and destroyed by them. The pharmacy's professional indemnity insurance arrangements were through the National Pharmacy Association (NPA) and this was due for renewal after 31 August 2019.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Pharmacy team members understand their roles and responsibilities. They keep their skills and knowledge up to date by completing regular training.

Inspector's evidence

The pharmacy dispensed approximately 4,000 prescription items every month with 13 people receiving their medicines inside multi-compartment compliance aids. In addition to the Essential Services, MURs and the NMS, the pharmacy also provided the NHS Urgent Medicine Supply Advanced Service (NUMSAS). There were no formal or commercial targets set to complete services.

Staff present included the regular pharmacist who was also the owner and a trained medicines counter assistant (MCA) who had completed a stock management course. This enabled her to put the pharmacy's dispensing stock away. Other staff included another MCA who was very recently employed and a trained dispensing assistant. Staff covered each other as contingency for annual leave or absence. They were a small team and described verbally discussing details. Appraisals were described as an informal process but ongoing feedback about staff progress was provided by the RP and staff felt supported by him.

Team members asked relevant questions to obtain necessary information before selling over-the-counter (OTC) medicines and they frequently ran details and all transactions past the RP. Ongoing training for the team was through the NPA, online resources and staff took instruction from the RP to keep their knowledge current.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy's premises are secure and provide an adequate environment to deliver its services.

Inspector's evidence

The pharmacy premises consisted of a medium sized retail area and a smaller dispensary. There was also an organised stock room upstairs in an attic area which was accessed by wooden stairs at the back of the dispensary. The ambient air temperature was appropriate, and the pharmacy was well-ventilated. The floor in the retail space could have been cleaner but it was raining on the day of the inspection and in general, the pharmacy was clean. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity to restrict their access by self-selection. There was also pet food and associated products sold in the pharmacy, that were close to the front counter.

There was limited space for dispensing processes to occur but there was appropriate space for medicines to be stored. The size of the dispensary also meant that not many people could be present at any one time. The pharmacy was situated in a listed building, hence the range of improvements which could be made was limited. This included increasing the size of the work surfaces as there was a total surface area of approximately 3.5 square metres as well as a sink and a draining board. Most of the work surface was occupied by paperwork, baskets containing prescriptions, and initially stock from the delivery. This was in the process of being put away. There were also crates of bulky medicines placed on the floor. Paperwork and prescriptions were piled up in an area near the dispensing checking area.

The pharmacist made extra provision for work space by using a loose shelf which he balanced between shelves on top of one section. This helped to assist with assembling compliance aids. Stock was checked off on the top of the filing cabinet and files could be placed here to read, if needed. In general, however, despite the limited work space available, the pharmacy's records were readily accessible and maintained appropriately.

A consultation area was at the back of the dispensary, and the room existed by sealing off the entrance with a sliding door. The space here was adequate, there was a sign on the door that this was a private consultation area but no sign in the retail space to indicate that a room was available for private conversations or services. The room could only be accessed through the dispensary or via the back door. There were dispensed prescriptions close to the entrance of the room and prescription only medicines (POMs) nearby. This meant access to POMs and sensitive information was possible. The RP explained that people were ushered directly into or out of the space.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy sources, stores and manages most of its medicines appropriately. The team is making some checks to ensure that medicines are not supplied beyond their expiry date. But, the pharmacy has no up-to-date written details to verify this for some medicines. And, it doesn't identify medicines that are approaching expiry. So, the team may not always be able to show that all stock is safe for supply. The pharmacy generally provides its services safely and effectively. But, team members don't always identify or record information when people receive higher-risk medicines. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied.

Inspector's evidence

There was a step at the front entrance and staff explained that they attended people here if they noticed that they required assistance. The pharmacy's opening hours were listed on the front door and there were two seats available for people waiting for prescriptions. The team described facing people who were partially deaf so that they could lip-read, and they provided written communication. Representatives were used to assist people who were visually impaired. Staff spoke slowly, used gestures and information on people's phones to assist them if their first language was not English.

The pharmacy was not presently supplying new people with multi-compartment compliance aids due to its space constraints. Prescriptions were ordered by the pharmacy for some people, when they were received, details were cross-referenced against records on the pharmacy system to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. Compliance aids were not left unsealed overnight and all medicines were de-blistered into compliance aids with none left within their outer packaging. Mid-cycle changes involved compliance aids being retrieved and new compliance aids being supplied. Staff supplied patient information leaflets (PILs) routinely and provided descriptions of medicines within compliance aids.

The pharmacy team used baskets to hold each prescription and associated medicines. This prevented any inadvertent transfer from occurring. Dispensed prescriptions awaiting collection were in general, attached to bags. Staff could identify fridge items and CDs (schedules 2 and 3) as these were highlighted. Schedule 4 CDs were not identified using any means, uncollected medicines were checked every month.

Staff were aware of the risks associated with valproate and there was relevant literature available that could be provided to patients at risk, upon supply of this medicine. Prescriptions for higher-risk medicines were not routinely identified to enable routine counselling or relevant parameters to be checked. The RP stated that people receiving these medicines from the pharmacy were occasionally asked about details. People prescribed warfarin sometimes bought in their yellow books so that the International Normalised Ratio (INR) could be looked at. This was not routine, and details were not documented to verify that this had occurred.

Licensed wholesalers were used to obtain medicines and medical devices. This included Alliance Healthcare, Doncaster, DE South, AAH and Trident. Unlicensed medicines were obtained through Avicenna or the Specials Laboratory. The team was aware of the process involved with the European Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed, scanners were

present, staff were trained through the RP and the pharmacy was trying to implement the process but the system was down.

Medicines were stored in an organised manner, staff frequently rotated stock and date-checked medicines for expiry on receipt from wholesalers, during the dispensing process and medicines in different sections were checked for expiry every few months. There was a schedule in place to demonstrate the process for OTC medicines but no schedule for dispensary stock. There were no date-expired medicines seen or mixed batches. However, short-dated medicines were not identified using any means. CDs were stored under safe custody. The key to the cabinet was maintained in a manner that prevented unauthorised access during the day and overnight. Medicines were stored evenly and appropriately within the pharmacy fridge. Drug alerts were received by email and through wholesalers. The team checked for stock and acted as necessary. There was an audit trail available to verify the process.

Once accepted, the team stored returned medicines requiring disposal within appropriate receptacles. There was a list available for the team to identify hazardous and cytotoxic medicines. People bringing back sharps for disposal were referred to the local council and CDs returned for destruction were brought to the attention of the RP. Relevant details were entered into a CD returns register.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the appropriate equipment and facilities it needs to provide services safely.

Inspector's evidence

The pharmacy held current versions of reference sources and necessary equipment. This included counting triangles and a separate one for cytotoxic medicines, an operating medical fridge, legally compliant CD cabinet and two crown-stamped conical measures for liquid medicines. One of the conical measures contained lime scale, ensuring this was removed was discussed at the time.

Computer terminals were positioned in a way that prevented unauthorised access and the team used cordless phones. This meant that conversations could take place away from the retail space if required. The dispensary sink used to reconstitute medicines was clean. There was hot and cold running water available as well as hand wash present.

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.	