General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Boots, 4-5 High Street, THAME, Oxfordshire, OX9 2BU

Pharmacy reference: 1035986

Type of pharmacy: Community

Date of inspection: 21/11/2019

Pharmacy context

This is a community pharmacy located on the main High Street in the centre of Thame, in Oxfordshire. The pharmacy dispenses NHS and private prescriptions. It offers Medicines Use Reviews (MURs), the New Medicine Service (NMS), seasonal flu vaccinations and a few private services to prevent malaria and hair loss. The pharmacy also provides multi-compartment compliance aids to people if they find it difficult to manage their medicines.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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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

The pharmacy generally manages risks in a satisfactory manner. Members of the pharmacy team understand how to protect the welfare of vulnerable people. They monitor the safety of their services by recording their mistakes and learning from them. The pharmacy adequately maintains most of the records that it needs to. And, the pharmacy generally protects confidential information appropriately. But it is not always recording accurate details for some of its records. This means that the team may not have all the information needed if problems or queries arise in the future. And, its team members are sharing their NHS smart cards to access electronic prescriptions. This makes it more difficult for them to control access to people's records and keep information safe.

Inspector's evidence

The pharmacy held a range of documented standard operating procedures (SOPs) to cover the services that it provided. They were dated from 2017 to 2019. Staff had read and signed the SOPs, they knew their responsibilities and the tasks that were permissible in the absence of the pharmacist. However, the matrix under the responsible pharmacist SOPs had not been completed to define the team's roles. The correct responsible pharmacist (RP) notice was on display and this provided details of the pharmacist in charge on the day.

Some of the pharmacy's workload was dispensed offsite. Staff explained that consent for this activity was obtained verbally and people were given the option to opt out of this service. There were also details on display to inform people that their prescriptions could be dispensed elsewhere. The team attached the company's pharmacist information forms (PIFs) to prescriptions so that relevant information could be easily identified. They processed one prescription at a time and the front dispensary was usually only used for walk-in trade. The RP accuracy-checked prescriptions from a designated area here, multi-compartment compliance aids and prescriptions to be dispensed off-site were processed from the second dispensary. This did not face the public and so helped reduce distractions.

Staff had recently started to record their own near misses as before the pharmacist did this on their behalf. The store manager explained that the pharmacy had a no blame culture, only a few near misses had recently been recorded and she had spoken to the team about this. Since the pharmacy had implemented a new system, the team's near misses had reduced. This was because incorrect medicines were picked up and highlighted when they were scanned into the system and before they had been dispensed. The store managed discussed mistakes with individual staff members to help them to learn from them and the near misses were collectively reviewed by her every month by completing the company's Patient Safety Review (PSR). A separate near miss log was kept in the second dispensary and PSR completed for mistakes associated with compliance aids.

After reviewing errors, internal processes were reinforced to the team such as asking for people's postcodes on handing out dispensed prescriptions. Medicines involved in errors were highlighted with caution stickers placed in front of them as an additional visual alert. Some look-alike and sound-alike medicines were identified in this way although when medicines had been moved on the shelves, some of the caution notes had not been re-arranged for example, the note alerting staff about Symbicort inhaler was currently placed in front of fluoxetine. Incidents were handled by pharmacists. The

procedure involved gathering relevant information, apologising, escalating if required, documenting details on the company's system and investigating. There was information on display in the retail area to inform people about the pharmacy's complaints procedure.

Staff could identify groups of people that showed signs of concern and who might require safeguarding. They were also trained as dementia friends. In the event of a concern, the RP would be informed. The team had been trained through completing an e-Learning module and staff in training had covered this from their course material. Both the regular pharmacists were trained to level two through the Centre for Pharmacy Postgraduate Education. One of their certificates to verify this was seen. The procedure to follow with contact details for the local safeguarding agencies were present. The company's chaperone policy was on display in the consultation room.

The front dispensary was open-plan and small. This meant that most of the dispensary was visible when people arrived at the dispensary counter. Staff explained that it was difficult to protect people's private information especially since the front panels had been removed and clear ones had been installed instead. To manage this, they spoke in lowered tones, they used the consultation room, confidential information was contained within the dispensary, turned over where possible and not left in areas that were available to the public. Sensitive details on dispensed prescriptions awaiting collection were not accessible from the front counter. Confidential waste was segregated into separate designated bins and disposed of through company procedures and staff had completed the company's mandatory information governance e-Learning training. Pharmacists accessed Summary Care Records for emergency supplies or for queries, consent was obtained verbally for this and details were recorded on people's records to verify this. In addition, information contained on an A5 piece of paper was provided to people after they accessed services (such as the flu vaccination service) and this outlined how their private information was processed.

However, there were no details on display to inform people about how the pharmacy maintained their privacy. Staff were using each other's NHS smart cards to access electronic prescriptions and their passwords were known. This was because of issues with unblocking their own cards. Although some of them had attempted to remedy this, the inspector was told that someone in the company had told staff that they could share their NHS smart cards. This is not an appropriate way to manage people's confidential information and this situation means that team members are not fully complying with the terms of agreement for use of their smart cards.

The team kept daily records of the minimum and maximum temperatures for the fridge and this verified that medicines were stored here appropriately. Staff also maintained a complete record of controlled drugs (CDs) that were returned by people and destroyed by them. The pharmacy held appropriate professional indemnity insurance to cover its services. Most of the pharmacy's other records were maintained in line with statutory requirements. This included a sample of registers seen for CDs, the RP record in general, records of emergency supplies and most records of unlicensed medicines. For CDs, balances were checked and documented every week. On randomly selecting CDs held in the cabinet, the quantities held matched the balances within the corresponding registers. There were occasional overwritten entries in the RP register and team members were recording incorrect prescriber information for some entries within the electronic private prescription record. Ensuring the pharmacy's record keeping routinely complied with legal requirements was discussed during the inspection.

Principle 2 - Staffing ✔ Standards met

Summary findings

Overall, the pharmacy has adequate numbers of staff to manage its workload. Pharmacy team members understand their roles and responsibilities. They are trained or undertaking appropriate training for their roles. And, the company provides them with resources to keep their skills and knowledge up to date.

Inspector's evidence

Staff present during the inspection included a regular pharmacist, the store manager who was also a pharmacist, two trained dispensing assistants and a trainee medicines counter assistant (MCA) who was enrolled onto accredited training in line with her role. The store manager explained that to help her with her management duties and whilst the influenza vaccination service was being provided, on one day every other week, additional pharmacist cover had very recently been provided. This was to help accuracy-check the compliance aids. Hence a locum pharmacist was also present to undertake this activity.

However, the staffing situation was somewhat stretched during the inspection. The regular pharmacist's time was completely taken up with providing the influenza vaccination service from the back to back appointments seen and a second pharmacist was necessary to cover the front dispensary. The pharmacy's ability to provide a seamless service would otherwise have been disrupted without this. The store manager therefore covered the front dispensary which took up time from her management duties. In addition, only one member of staff was present to manage each of the different sections. The trainee MCA was managing the counter, one dispensing assistant was based in the front dispensary and the other was in the rear. The pre-registration pharmacist was on a training day and another dispensing assistant was on annual leave. According to staff, the inspection took place on a 'quieter day' because one of the local surgeries was closed. However, there was still a steady stream of people attending the pharmacy and queues did build. The team acknowledged people appropriately, but because of the lack of additional staff, they were stretched, and people were having to wait for longer than usual.

The inspector was told that there was no contingency to cover members of the pharmacy team when they were on leave. Team members managed the workload by routinely staying late after work on their own volition. They were described as dedicated and worked hard to ensure routine tasks were regularly completed. One experienced and long-standing member of staff was due to be relocated to another local branch for three months and the pharmacy was due to have an apprentice starting in lieu of this. Overall, the pharmacy's current staffing levels means that they can struggle with the workload. Additionally, if there are no contingency arrangements in place to cope with staff absence, this could make the situation worse. The company should ensure that it assesses the staffing profile and implements appropriate measures to ensure its workload is manageable and safe going forward.

There were targets set to complete services such as influenza vaccinations and MURs. The latter was described as manageable, the team did not meet the allocated target in the year before for the former service. The targets did not affect the professional judgement of the staff, but the services provided were observed to place a strain on the team during the inspection. The company should ensure that in line with the standards set by the GPhC, incentives or targets do not compromise the health, safety or wellbeing of the public, or the professional judgement of the team.

Staff wore name badges outlining their roles. The team's certificates to demonstrate qualifications obtained were not seen. The trainee MCA asked relevant questions before over-the-counter (OTC) medicines were sold, she provided advice and checked with the RP appropriately. Team members in training were provided with set aside time to complete their studies. To assist with training needs, the company provided staff with e-Learning modules, training packs, newsletters and updates. They also read relevant literature. Staff progress and appraisals were conducted every three months. There were noticeboards in the pharmacy and the store manager also communicated information verbally to the team. Team meetings were held when required.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide an adequate environment for the delivery of healthcare services. The pharmacy is secure with a private area for conversations and services to take place.

Inspector's evidence

The pharmacy consisted of a medium sized retail area and a much smaller, open plan, dispensary. The latter was used to dispense and check walk-in prescriptions. There was limited space for dispensing activity to take place or for large quantities of stock to be stored here. However, there was a separate dispensary located in staff-only areas. This was used to assemble compliance aids and stored bulkier items as well as excess stock. There was key coded access into this dispensary and staff areas.

The pharmacy was clean, suitably lit, appropriately presented and ventilated. Some of the fixtures and fittings were dated but still functional. Pharmacy (P) medicines were stored behind the front pharmacy counter. Staff were always within the vicinity to help prevent these medicines from being self-selected. A signposted consultation room was available for private conversations or services. This was located inside a corridor that led to the second dispensary and store room, access into this area was restricted. The room was of an appropriate size for its intended purpose. However, the corridor leading to the room detracted from the overall professional appearance. The paint here was peeling and marked as was the floor which was also scuffed. Staff stated that they had very recently been given authorisation to paint this themselves instead of their maintenance department dealing with the situation.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are largely delivered in a safe manner. Its team members are helpful. The pharmacy obtains its medicines from reputable sources. It usually stores and manages most of its medicines appropriately. Team members routinely identify people receiving higher-risk medicines. They ask relevant questions, but they don't always record this information or enough details to show that they have considered the risks when some medicines are supplied inside compliance aids. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. And, the pharmacy has no designated containers to store and dispose of some medicines that could be harmful to the environment.

Inspector's evidence

There were two front entrances into the pharmacy, one was via a step and the second through an automatic door at street level. There was clear, open space and wide aisles inside the premises which enabled people using wheelchairs to easily access the pharmacy's services. Two seats were available for people waiting for prescriptions. Staff described providing written communication for people who were partially deaf and there was a hearing aid loop that they knew how to use. Team members explained that they took their time to support people who were visually impaired and verbally explained or read information to them if required. Both the front medicines and dispensary counter contained documented information and literature about the vaccinations being provided from the pharmacy. There was a selection of leaflets available about the services provided from the pharmacy and a signposting document for other local providers in the area was seen although this was dated from 2016 to 2017.

Both pharmacists mentioned MURs being a beneficial service for people. The pharmacy served a high proportion of people who were elderly and struggled with taking their medicines. The service had therefore helped people to take their medicines as prescribed. Examples provided included pharmacists counselling people with asthma about their inhaler use. In addition to the SOPs, the pharmacy held the relevant paperwork for the Patient Group Directions (PGDs). The latter had been signed by the pharmacists authorised to make the supply. The pharmacist's declaration of competence for the influenza vaccination service was also seen.

The influenza vaccination service was provided via appointments only. This helped manage the workload and was described as a convenient and an easily accessible service for people because the local GP's were only offering appointments on Saturdays. The latter was not always possible for everyone to attend. Both pharmacists had completed the appropriate training to provide the service, this included vaccination techniques and anaphylaxis. There was also suitable equipment to safely provide the service such as a sharps bin and adrenaline in the event of a severe reaction to the vaccine. At the time of the vaccination, staff were responsible for people completing the necessary paperwork and inputting details of the supply on the system. The appropriate flu vaccine was taken out of the fridge by staff, checked against information that was displayed in front of the fridge and double-checked by the pharmacist before administering. Informed consent was obtained from people before vaccinating and details were sent to their GP.

During the dispensing process, staff used plastic tubs to hold prescriptions and medicines and this

helped to prevent the inadvertent transfer of items. A dispensing audit trail was used to identify the staff involved. This was through a facility on generated labels and a quad stamp that was used on prescriptions. Dispensed prescriptions awaiting collection were stored within an alphabetical retrieval system. The team identified fridge items, CDs (Schedules 2 to 4) and when pharmacist intervention was required with stickers, PIFs and laminate cards. Clear bags were used to hold assembled fridge items and CDs to assist in identifying the contents when they were handed out to people.

Staff were aware of the risks associated with valproates and there was guidance material available to provide to people at risk. The pharmacy had completed an audit in the past and were due to re-initiate this. People at risk identified as having been supplied this medicine were routinely highlighted, counselled and educational material provided. People prescribed higher-risk medicines were identified, counselled and relevant parameters were routinely checked. This included checking the International Normalised Ratio (INR) levels for people prescribed warfarin and asking about blood test results. However, the pharmacy team was not routinely recording this information which would help to verify that this was happening.

Offsite dispensing involved repeat dispensing prescriptions. The prescriptions were dispensed through the pharmacy's system and the details transmitted to the dispensing support pharmacy (DSP) in Preston. Prescriptions were clinically checked by a pharmacist before details were transmitted. The pharmacy retained the prescriptions at the pharmacy and any prescriptions for CDs, fridge lines, split packs of medicines, cytotoxic or bulky medicines were not sent for dispensing. Dispensed prescriptions were sent back within two working days. Staff then matched people's details on the bags to prescriptions and the bags were not opened. If people arrived to collect their medicines before their dispensed prescriptions had returned from DSP, the team dispensed them at the pharmacy. This also happened when items were owing.

Compliance aids were supplied to approximately 200 people in their own homes. They were initiated after the pharmacist completed an assessment to determine people's suitability for this. Once this had been approved, prescriptions were ordered by the pharmacy and when received, details were cross-referenced against people's individual records to help identify any changes or missing items. Queries were checked with the prescriber and audit trails were maintained. Staff ensured that all medicines were de-blistered into the compliance aids with none left within their outer packaging. Descriptions of the medicines inside the compliance aids and patient information leaflets (PILs) were routinely provided. Mid-cycle changes involved either new medicines being supplied separately, the compliance aids were retrieved, amended, re-checked and re-supplied or new compliance aids were provided.

However, staff were dispensing sodium valproate in the compliance aids for four weeks supply at a time. They were aware of stability concerns with this medicine and mentioned receiving a safety alert about this from their head office. The team explained that this practice was necessary to ensure that people would take their medicine as prescribed by their doctor and conversations had been held with the prescriber. However, there were no details documented to confirm this. Nor was there any evidence that the pharmacy had carried out any risk assessment about this situation.

Licensed wholesalers such as Alliance Healthcare and AAH were used to obtain medicines and medical devices. Unlicensed medicines were obtained from AAH. The pharmacy had recently updated its system to help comply with the European Falsified Medicines Directive (FMD). Medicines were date-checked for expiry every week and the team used a date-checking schedule to verify when this process was carried out. Short-dated medicines were identified using stickers, liquid medicines were marked with the date upon which they were opened and there were no date-expired medicines or mixed batches seen. However, there were several poorly labelled containers present where medicines had been

stored outside of their original containers and had not been annotated with the full details (such as batch numbers and expiry dates). This was discussed at the time. Medicines were stored evenly in the fridge. CDs were stored under safe custody and keys to the cabinet were maintained in a manner that prevented unauthorised access during the day as well as overnight. Drug alerts and product recalls were received through the company, stock was checked, and action taken as necessary. The pharmacy kept an audit trail to verify this.

Medicines returned for disposal, were accepted by staff and stored within designated containers. However, there was no list available for the team to identify hazardous and cytotoxic medicines that required disposal and no designated containers to store them. People returning sharps for disposal were referred to their GP surgery. Returned CDs were brought to the attention of the RP and segregated in the CD cabinet before their destruction. Relevant details were entered in a CD returns register.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has an appropriate range of equipment and facilities to provide its services safely. The equipment is clean and well maintained.

Inspector's evidence

The pharmacy held an appropriate range of equipment and facilities that it needed for its services. This included current versions of reference sources, a range of clean, standardised conical measures for liquid medicines, a counting triangle with a separate one for cytotoxic medicines and a capsule counter. The CD cabinet was secured in line with statutory requirements and the medical fridges appeared to be operating appropriately. The dispensary sink used to reconstitute medicines was clean. There was hand wash and hot as well as cold running water available. Staff could store their personal belongings inside lockers. The pharmacy's computer terminals were password protected and positioned in a manner that prevented unauthorised access.

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.