

Registered pharmacy inspection report

Pharmacy Name: Windmill Pharmacy, 19-21 High Street, Ivinghoe,
LEIGHTON BUZZARD, Bedfordshire, LU7 9EP

Pharmacy reference: 1124131

Type of pharmacy: Community

Date of inspection: 24/05/2019

Pharmacy context

This is a community pharmacy located within the village of Ivinghoe, near Leighton Buzzard, in Bedfordshire. A range of people use the pharmacy's services. The pharmacy dispenses NHS and private prescriptions. It provides Medicines Use Reviews (MURs), the New Medicine Service (NMS), flu vaccinations during the season and supplies Champix to help people quit smoking. The pharmacy also provides people with multi-compartment compliance aids, if they find it difficult to take their medicines on time.

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 identifies and manages most risks effectively. Members of the pharmacy team monitor the safety of their services by recording mistakes and learning from these. In general, the pharmacy maintains most of its records in accordance with the law. And, the team protects people's privacy well. But, team members don't understand how they can help to protect the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately.

Inspector's evidence

The pharmacy was organised, and it was kept clear of clutter. The responsible pharmacist (RP) confirmed that there was an established workflow in place. Pharmacists processed prescriptions to generate labels, staff then selected stock and assembled prescriptions into baskets, these were placed on one side of the dispensary and when the RP was ready to conduct the final check, the baskets were moved into a segregated area. The RP also ensured that he took a mental as well as a physical break before conducting the final check for accuracy.

The pharmacy team's near misses were routinely recorded. Staff identified medicines with similar packaging and segregated look alike and sound alike drugs (LASA), this included separating atorvastatin and simvastatin, salbutamol inhaler and the breath-actuated version as well as moving bisoprolol 10mg and 2.5mg away from one another. Every month, the RP completed a patient safety report, he discussed his findings with the team and the other regular pharmacist. This helped to raise staff awareness. Key learning points were recorded within these reports and feedback was provided to the staff.

The pharmacy's complaints procedure was on display. Pharmacists handled incidents. A documented complaints procedure and previous incident report forms were present to verify the process. The RP explained that details were checked, an apology was issued, the situation was rectified, and the person involved was kept informed of the outcome. The level of harm that occurred was checked and if anything was taken incorrectly, the person's GP was informed.

A notice was on display to inform people about how their privacy was maintained. Sensitive details from assembled prescriptions that were awaiting collection, could not be seen from the retail space and staff shredded confidential waste. They were trained on the General Data Protection Regulation (GDPR), team members had read through associated paperwork and completed a workbook. Staff had also signed confidentiality agreements. Summary Care Records were accessed for emergency supplies or for queries about people's medicines, consent was obtained verbally to access this.

A range of documented standard operating procedures (SOPs) were present to support the provision of services. Some of the SOPs were from 2016 and due for review in 2018 and some were from 2017 and due for review in 2019. There was also a set of SOPs from the National Pharmacy Association (NPA) that the pharmacy was in the process of implementing. Staff had read and signed the first set of SOPs and their roles and responsibilities were defined. The correct RP notice was on display and this provided details of the pharmacist in charge on the day. Staff knew which activities were permissible in the absence of the RP and the process to take if the pharmacist failed to arrive.

Pharmacists were trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE) and the RP described attending a course with the Local Pharmaceutical Committee. There were local contact details and policy information present as well as an SOP to help provide guidance to the team. However, staff were not trained to safeguard vulnerable people. On prompting, they would refer to the pharmacist in the event of a concern.

Records for the minimum and maximum temperatures for the fridge were maintained every day and these were within the appropriate range. The team maintained a complete record for the receipt and destruction of controlled drugs (CDs) that were brought back by the public.

Most of the pharmacy's records were held in line with statutory requirements. This included a sample of registers for CDs that were checked, records of private prescriptions, unlicensed medicines, and emergency supplies. Balances for CDs were checked, and details documented every month. On checking a random selection of two CDs, quantities held, matched the balance entries in corresponding registers.

There were gaps in the electronic RP register where pharmacists had failed to record the time that their responsibility ceased.

The pharmacy was appropriately insured. This included its professional indemnity insurance which was through Numark and due for renewal after November 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 4,500 to 5,000 prescription items every month and 15 to 20 people were provided with multi-compartment compliance aids.

Staff present included one of the regular pharmacists who was also a co-owner and a dual trained dispensing and counter assistant. There were also two further dual trained dispensing and counter assistants, another regular pharmacist and co-owner as well as a trained medicines counter assistant (MCA) who would be placed on a dispensing assistant's course in the future.

The staff's qualifications obtained through accredited routes were seen. The member of staff asked a range of suitable questions to determine suitability before medicines were sold over the counter and she was knowledgeable about these medicines. This team member described refusing sales where abuse was suspected and people purchasing excess amounts of medicines were monitored.

Staff described keeping their knowledge relevant and learning about updates through pharmacist instruction, they completed e-Learning and workbooks that were provided by the pharmacists as well as training from Numark. Formal appraisals to check on staff progress occurred annually. As they were a small team, staff members communicated verbally with one another. The RP explained that there were no formal targets in place to achieve services.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy's premises provide a professional environment to deliver its services.

Inspector's evidence

The premises consisted of a medium sized retail space and a spacious dispensary at the rear. There was also an appropriately sized, signposted, consultation room available to one side of the retail area. This allowed services and confidential conversations to take place. There were two entrances into this space, one was from the dispensary and the other, from the retail area. The latter was kept locked with key-coded entry required. There was no confidential information readily accessible from within the room.

The pharmacy was bright and well-ventilated. Its retail area was professional in appearance although the carpet could have been cleaner. Staff explained that they routinely ensured the pharmacy was kept clean and vacuumed every day. Pharmacy only (P) medicines were stored behind the front counter and this, along with a drop-down barrier limited their access by self-selection. It also prevented unauthorised entry into the dispensary.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy obtains its medicines from reputable sources and in general, stores them appropriately. The pharmacy provides its services safely and effectively. Team members highlight prescriptions that require extra advice and they take extra care with high-risk medicines. This helps ensure that people can take their medicines safely.

Inspector's evidence

People could enter the pharmacy through a wide, front door and sloped entry from the street. This, coupled with the clear open space inside the premises, facilitated easy entry for people requiring wheelchair use. Staff described attending people with restricted mobility at the door, if this was required and the RP explained that the owners had changed the pharmacy's entry point and front door to improve access arrangements for people. There were two seats for people waiting for prescriptions. Staff explained that they spoke clearly to help communicate with people who were partially deaf, people were verbally counselled if they were visually impaired and their understanding was checked.

The pharmacy's opening hours were advertised on the front door and there was a range of leaflets available about other services. There was also documented information present that staff could use, to signpost people to other local organisations.

During the dispensing process, team members used a dispensing audit trail through a facility on generated labels and this identified their involvement in processes. Staff used baskets to hold prescriptions and associated medicines. This helped prevent any inadvertent transfer.

Staff were aware of risks associated with valproate. They had read relevant material on this and had not seen any people who may become pregnant prescribed this medicine. Relevant literature was available to provide to people, if required. For people prescribed higher risk medicines, appropriate questions were routinely asked. This included asking about blood test results or the International Normalised Ratio (INR) level for people prescribed warfarin. The team also documented relevant details.

Assembled bags awaiting collection were stored with prescriptions held within an alphabetical retrieval system. Details about fridge items and CDs (schedules 2, 3 and 4) were identified to help staff to identify them. Uncollected prescriptions were checked every month. A colour co-ordinated audit trail was also in operation to help identify which members of staff had stored prescriptions.

A prescription for diazepam, dated 23 April 2019 was present in the retrieval with no method used to identify its CD status or 28 day prescription expiry. The RP explained that schedule 4 CDs were normally routinely identified.

Multi-compartment compliance aids were supplied to people after the RP assessed suitability. Once set up, staff ordered prescriptions and when received, they cross-referenced details against records on the pharmacy system as well as the repeat prescription request to help identify changes or missing items. The team checked queries with the prescriber and maintained records to verify this. Compliance aids were not left unsealed overnight, descriptions of medicines within compliancer aids were provided and all medicines were de-blistered into compliance aids with none left within their outer packaging. Patient

information leaflets (PILs) were routinely supplied. People prescribed warfarin were provided this separately and details about INR levels were documented. Mid-cycle changes involved retrieving the old compliance aids, amending them, re-checking and re-supplying to people.

The pharmacy team delivered medicines. Staff maintained records of when and where medicines were delivered, this included identifying CDs and fridge items. Signatures were obtained from people once they were in receipt of their medicines. Failed deliveries were brought back to the pharmacy, notes were left to inform people of the attempt made and medicines were not left unattended.

The pharmacy obtained its medicines and medical devices from licensed wholesalers such as Phoenix, AAH, Lexon and Colorama. Unlicensed medicines were obtained through AAH. Staff were aware of processes involved with the European Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed and the owners were currently in the process of looking at systems and internal processes.

Team members stored medicines on shelves in an ordered manner. They date-checked medicines for expiry every month and an up-to-date schedule was seen to verify that the process had occurred. Medicines approaching expiry were highlighted with stickers and a book was used to record details. There were no date-expired medicines seen or mixed batches of medicines present. 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.

A bottle containing loose omeprazole capsules was seen placed inside the original pack but without a label to indicate its contents, expiry date or batch number. This was discussed at the time and a poorly labelled bottle containing rivaroxaban tablets was disposed of during the inspection.

Medicines that were returned by people for disposal were held within appropriate containers prior to their collection. People bringing back sharps for disposal were referred to the GP surgery. Relevant details were taken about returned CDs, these were brought to the attention of the RP.

Drug alerts were received via email; the process involved checking for stock and taking appropriate action as necessary. There were records present to verify the process.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

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

Inspector's evidence

The pharmacy was equipped with a range of current versions of reference sources. Crown-stamped conical measures were available for liquid medicines, staff could use clean, counting triangles and a blood pressure machine was present. This was replaced within the last two years.

The dispensary sink used to reconstitute medicines was clean, there was hot and cold running water with hand wash available. The fridge used for medicines requiring cold storage was operating at appropriate temperatures. The CD cabinet was secured in line with legal requirements.

Computer terminals in the dispensary were positioned in a manner that prevented unauthorised access. Staff held their own NHS Smart cards to access electronic prescriptions. These were taken home overnight, and a shredder was available to dispose of confidential waste. Cordless phones were present, and this helped ensure confidential conversations could take place away from the retail space.

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.