

Registered pharmacy inspection report

Pharmacy Name: Wedmore Pharmacy, 1 Church Street, WEDMORE,
Somerset, BS28 4AB

Pharmacy reference: 1036369

Type of pharmacy: Community

Date of inspection: 01/05/2019

Pharmacy context

This is a community pharmacy located within the village of Wedmore in Somerset. A range of people use the pharmacy's services, this includes a high proportion of older people. The pharmacy dispenses NHS and private prescriptions. It supplies some people with their medicines inside multi-compartment compliance packs, if they find it difficult to take their medicines on time.

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

The pharmacy manages some of the risks associated with its services appropriately. It has written instructions to help with this. But, members of the pharmacy team have not read them and some of its instructions were missing altogether. This could mean that staff may not be following the most up-to-date procedures. Pharmacy team members deal with their mistakes responsibly. But, they may not be recording all the details. This could mean that they may be missing opportunities to spot patterns and prevent similar mistakes happening in future. Whilst the pharmacy team has some understanding of data protection, the pharmacy doesn't tell people what it does with their personal information, as required by law. And, not all the team members understand how they can help to protect the welfare of vulnerable people. So, they may not know how to respond to concerns appropriately. The pharmacy does not always maintain records that must be kept, in accordance with the law. This means that team members may not have all the information they need if problems or queries arise.

Inspector's evidence

The pharmacy had very recently changed ownership (April 2019) and it was in a transitional period. There was enough space for the team to dispense prescriptions safely. However, except for the retail space, the pharmacy was cluttered at the point of inspection (see Principle 3). Staff assembled prescriptions in a segregated area and the final check by the Responsible Pharmacist (RP) also occurred from a separate space. The team described making sure that they kept the shelves tidy. This was to help prevent mistakes occurring and if they noticed look-alike or sound-alike medicines, they made each other aware.

Staff stated that they did record near misses. There were no near misses seen recorded as no-one could locate the forms being used to record these. According to the RP, the process involved sending these to the pharmacy's head office who reviewed near misses, collated the information and relayed this back to their branches every month.

There was no information on display about the pharmacy's complaints procedure. This meant that people may not have been able to raise their concerns easily. A documented complaints process was present. The RP's process to handle incidents was in line with this.

Staff had not seen, read or signed any of the new company's Standard Operating Procedures (SOPs) at the point of inspection. These were present. However, some SOPs were missing. This included an SOP for safeguarding, for the assembly of Monitored Dosage Systems (multi-compartment compliance packs) and for higher-risk medicines.

Some team members could identify signs of concern to safeguard vulnerable people. They were trained through reading the previous owner's documented information. Newer members of staff were not trained on this. Both pharmacists were trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE). Dispensing staff were aware of relevant local contact details although these could not be located at the inspection.

There was no confidential material stored in areas that faced the public. The team segregated confidential waste before it was taken away by the company for destruction. Bagged prescriptions awaiting collection were stored in a location that prevented sensitive information being visible from the

retail area. Dispensing staff were trained on the EU General Data Protection Regulation (GDPR) through the previous owners. However, there was no information available to inform people about how their privacy was maintained.

The correct RP notice was on display. This provided details of the pharmacist in charge of operational activities. From its current position, the details were not clearly visible to people standing in the retail space. A sample of registers checked for Controlled Drugs (CDs) were maintained in line with the Regulations. There were no documented checks of balances for CDs since the change of ownership but there were ticks next to the running balances seen. On randomly selecting two CDs held in the cabinet, their quantities matched balances recorded in corresponding registers. Most records of emergency supplies were documented with the nature of the emergency, odd entries were missing this information. For the past month, there were gaps seen within the electronic RP record where pharmacists had not recorded the time that their responsibility ceased.

There were two registers seen for private prescriptions. There were no documented entries in the bound register since April 2019. Staff stated that this was the register being used. There were four entries seen on the electronic private prescription register from April which indicated that supplies had been made against private prescriptions in this time frame. Prescriber details were incomplete in the electronic private prescription register. Professional indemnity insurance was through Numark and due for renewal after January 2020.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has an adequate number of staff to manage its workload. Trained staff understand their roles and responsibilities. But, newer members of the team lack some knowledge of the pharmacy's processes. This could affect how well the pharmacy cares for people or the advice it gives.

Inspector's evidence

The pharmacy dispensed 6,000 prescription items every month with 15 people receiving their medicines inside multi-compartment compliance packs. Staff present included two locum pharmacists, two trained dispensing assistants and a newly employed medicines counter assistant (MCA). The latter's employment had commenced within the last month after the change of ownership and the MCA was not currently enrolled onto any accredited training for her role. There was also another trained MCA who, according to staff was due to be enrolled onto accredited training for dispensing as well as a delivery driver, who was shared between the company's other branches.

The RP explained that the pharmacy was currently recruiting for staff, but the owners were encountering difficulty due to its rural location. The newly employed MCA knew that the pharmacy could not open if the RP failed to arrive and would not sell any medicines in the RP's absence. However, the MCA stated that she would hand out assembled medicines if the RP was absent because these had already been checked.

The MCA asked a range of questions to obtain relevant information before selling over-the-counter (OTC) medicines and checked every transaction, sale or request with the RP. Locum pharmacists had not been set any formal or commercial targets to achieve services.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is secure and well maintained. It provides a satisfactory environment for the delivery of pharmacy services. But, it is cluttered which increases the risk of accidents or mistakes occurring.

Inspector's evidence

The premises consisted of a medium sized retail area and a main dispensary at the rear. There were extensive storage facilities at the back and upstairs as well as a second segregated dispensary used to assemble multi-compartment compliance packs upstairs.

The pharmacy was suitably lit and well ventilated. The retail space was clean and generally well presented but there were some gaps where there was no stock present. Pharmacy only (P) medicines were currently stored in unlocked Perspex units in the retail space. The MCA was always present to intervene. The RP mentioned the company moving these behind the front counter to help restrict access by self-selection.

Both dispensaries and back areas of the pharmacy were cluttered. The staff WC was littered with toilet paper and required cleaning. This was unhygienic and discussed with the RP at the time. A signposted consultation room was available to provide services and private conversations. The space was of a suitable size for the services provided. The door was unlocked. There was no confidential information present.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy obtains medicines from reputable sources, but it doesn't always make sure that they are safe to use. Some medicines are stored in poorly labelled containers. This makes it harder for the team to check the expiry date, assess the stability or take any necessary action if the medicine is recalled. The pharmacy team are not making any checks to ensure the fridges used to store medicines are working properly. So, they may not always be able to demonstrate that medicines have been appropriately stored. And, the pharmacy has not made any checks to ensure that medicines are not supplied beyond their expiry date since its ownership changed. It has no up-to-date written details to demonstrate this. So, the team may not always be able to provide assurance that all stock is fit for purpose. Some of the pharmacy's services are delivered in a safe manner. But, team members do not always identify prescriptions that require extra advice. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. And, they are not removing date-expired prescriptions in time. This means that medicines could be supplied unlawfully. The pharmacy delivers prescription medicines safely to people's homes and keeps records of this. But, people can see other people's private information when they sign to receive their medicines. Team members fill compliance packs then sometimes leave them unsealed while they wait for them to be checked. This means the medicines are not very well protected if left overnight and could be damaged or contaminated by insects or dust. It may also increase the risk of mistakes happening.

Inspector's evidence

The pharmacy's front door was wide and there was clear, open space inside the premises. This helped people requiring wheelchair access to easily use the pharmacy's services. There were two seats available for people waiting for prescriptions. Staff described facing people who were partially deaf, they would repeat details and check their understanding. Medicines with braille were supplied to people who were partially sighted. The pharmacy team used baskets to hold each prescription and associated medicines. This prevented any inadvertent transfer. Staff used a dispensing audit trail to verify their involvement in processes. This was through a facility on generated labels.

Staff were aware of risks associated with valproate. They had read information about this and literature was present to provide to people if needed. The team explained that no prescriptions for people in the at-risk group had been seen.

Multi-compartment compliance packs were being prepared in a cluttered environment. There were packs present that had been left unsealed for the past few days. Staff described ordering prescriptions on behalf of people receiving the packs and when these were received, they checked details against individual records to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. However, not all records were up to date. Descriptions of medicines within the packs were provided. Patient Information Leaflets (PILs) were routinely supplied. All medicines included in the packs were de-blistered and removed from their outer packaging. Some people with the packs received warfarin separately. There were no relevant checks being made about their International Normalised Ratio (INR) level or details seen documented about this. Mid-cycle changes involved the packs being retrieved and a new set of packs supplied.

Some people's prescriptions were being delivered. The pharmacy was currently offering a reduced service on three days of the week. The team were maintaining audit trails to demonstrate when and

where medicines were delivered. CDs and fridge items were identified. The driver obtained people's signatures when they were in receipt of their medicines. However, there was a risk of access to confidential information when people signed. This was from the way people's details were laid out on the forms being used. Failed deliveries were brought back to the pharmacy with notes left to inform people about the attempt made. Staff stated that the driver did not leave medicines unattended.

Prescriptions for people prescribed higher-risk medicines were not identified to enable pharmacist intervention, counselling or to check relevant parameters. Relevant information such as the INR level for people prescribed warfarin were not routinely being checked or details recorded.

Prescriptions requiring collection were held within an alphabetical retrieval system. Fridge items and CDs (Schedules 2 and 3) were identified with stickers. Schedule 4 CDs were not highlighted. Uncollected medicines had not been checked or removed since the change of ownership. Date expired prescriptions were present. This included expired prescriptions for zolpidem and pregabalin from March 2019 that had not been removed from the retrieval system. The MCA did not know how long prescriptions were valid for, she could not identify prescriptions for CDs without stickers present and did not know that these prescriptions were only valid for 28 days.

Licensed wholesalers were used to obtain medicines and medical devices. This included AAH, Alliance Healthcare and Phoenix. The pharmacy's head office centrally sourced unlicensed medicines. The pharmacy was in the process of complying with the European Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed. Relevant equipment had been ordered and staff were somewhat aware of the processes involved. There was no guidance information seen to help support the process.

Medicines were generally stored in an organised manner in the dispensary. 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. Staff stated that medicines had not been date-checked for expiry since the change of ownership. They explained that a stock-take had occurred in January and that the team had checked the whole dispensary under the previous owners. The schedule seen for this process demonstrated that the last date-checks occurred in January 2019. Stickers were used to identify short-dated medicines and the team identified these medicines three to five months before their expiry was due. There were no date-expired medicines or mixed batches seen.

There were odd medicines stored outside of their original containers that were not marked with all relevant details (four packs of trazodone, Galfer syrup and Ditropan). Expiry dates and batch numbers were missing from these. Loose blisters of medicines were seen (Pradaxa). Odd uncapped bottles were present in the dispensary. This meant that potential contamination from insects or dust was possible.

Records for the maximum and minimum temperatures for both fridges were not being routinely checked or details documented. The last documented details seen were from January 2019 and December 2018. It was therefore not possible to determine whether medicines requiring cold storage were being stored and maintained within a suitable environment.

A mound of returned medicines was seen stored in one location. There were appropriate receptacles available to process these. Counter staff did not know the process involved for people bringing back sharps for disposal and they did not know about or could not identify returned CDs. They took all returned medicines and showed them to dispensing staff. Drug alerts were received by email. The process involved checking for stock and acting as necessary.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

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

Inspector's evidence

The pharmacy was equipped with current versions of reference sources. Computer terminals were positioned in a way that prevented unauthorised access. Staff were using their own NHS smart cards to access electronic prescriptions. These cards were taken home overnight. Clean, crown stamped conical measures were present for liquid medicines. Counting triangles were available.

The dispensary sink used to reconstitute medicines could have been cleaner. There was hot and cold running water available as well as hand wash present. Medical fridges were available to store medicines. See Principle 4 regarding the temperature of these. The CD cabinets were secured in line with legal requirements. The blood pressure machine was last replaced in 2017 according to the information present on the machine.

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.