General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Edlesborough Pharmaceutical Supplies Ltd, 11 Cow Lane, Edlesborough, DUNSTABLE, Bedfordshire, LU6 2HT

Pharmacy reference: 1087356

Type of pharmacy: Community

Date of inspection: 24/05/2019

Pharmacy context

This is a community pharmacy located next to a GP surgery and within a residential area, in the village of Edlesborough in Bedfordshire. Mainly older people use the pharmacy's services. The pharmacy dispenses NHS and private prescriptions. It provides Medicines Use Reviews (MURs) and the New Medicines Service (NMS). And, it supplies some people with their medicines inside multi-compartment compliance aids for people who 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

In general, the pharmacy manages risks effectively. When things go wrong, team members deal with mistakes responsibly. But, they don't always 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. But, 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 was small with limited space to dispense prescriptions (see Principle 3). The workflow involved prescriptions for people waiting, being passed through a hatch from the counter to the dispensary. These prescriptions were prioritised, staff assembled them on the front bench alongside the Responsible Pharmacist (RP) who provided the final accuracy-check.

Staff described checking expiry dates during the assembly process and they ensured workspaces were clear before they dispensed prescriptions. The team's near misses were pointed out to them and the RP explained that these were recorded on Pharmapod. He had not noticed any trends or patterns occurring. Staff stated that a low level of near misses occurred, and this was because they were trained through accredited routes and experienced in their roles. They also described highlighting common errors such as gabapentin and pregabalin. The RP described near misses being reviewed every month and annually although the review of these was last seen documented in August 2018.

There was information on display about the pharmacy's complaints procedure. The RP's process to handle incidents involved checking details, speaking to staff, informing the person's GP if anything was taken incorrectly and documenting details. This included reporting details to the National Reporting and Learning System (NRLS).

There was a range of electronic Standard Operating Procedures (SOPs) available to support the supply of services. This included a documented SOP to cover the accuracy-checking process for the technician. These were in the process of being implemented and were dated from 2019. Staff had not yet read and signed all the SOPs. The team knew which activities were permissible in the absence of the RP and the correct RP notice was on display. This provided details of the pharmacist in charge on the day.

Team members could identify signs of concern to safeguard vulnerable people. They were trained through reading relevant information and had completed a module via Numark. Staff were also trained as dementia friends and explained that in the event of a concern, they would refer to the RP. The RP and technicians were trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE).

There was a notice on display to inform people about how the pharmacy maintained their privacy. This also included a separate notice to inform them of the availability of a private space if this was required. The team ensured that no confidential material was left in areas that were accessible to the public. Confidential waste was segregated before being taken away by an authorised carrier. Dispensed prescriptions awaiting collection were stored in a location that prevented sensitive information being visible from the retail area. Staff were trained on the EU General Data Protection Regulation (GDPR).

The RP had accessed Summary Care Records for queries and obtained consent to do this, verbally. Notes were also recorded on people's records as additional verification.

The team kept records of the minimum and maximum temperature for the fridge every day. This demonstrated that appropriate storage of medicines occurred here. Staff also maintained a full record of the receipt and destruction of Controlled Drugs that were brought back by the public for disposal.

There were odd gaps within the electronic RP record where pharmacists had not recorded the time that their responsibility ceased. Records for emergency supplies were seen with details about the nature of the emergency recorded, although some records were only marked as "script to follow". This was discussed during the inspection.

A sample of registers checked for Controlled Drugs (CDs) were mostly maintained in line with the Regulations. Incomplete addresses of wholesalers were recorded, the pharmacy only recorded the last four digits of the invoice number and odd details of amendments were incomplete. Balances for CDs were checked with every transaction and on randomly selecting CDs held in the cabinet (Longtec, Zomorph), their quantities matched balances recorded in corresponding registers.

Prescriber details were missing from records of unlicensed medicines and there were missing records of prescribers in the electronic private prescription register or incorrect details about prescribers seen recorded. Professional indemnity insurance arrangements was provided through Numark and due for renewal after September 2019.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Members of the pharmacy team understand their roles and responsibilities. And, they complete ongoing training to help keep their skills and knowledge up to date.

Inspector's evidence

The pharmacy dispensed 9,000 prescription items every month with 30 people receiving their medicines inside Monitored Dosage Systems (MDS). Staff present included the pharmacist who was also the superintendent, a trained medicines counter assistant (MCA), pharmacy technician and an Accuracy Checking Technician (ACT). Other staff included another two MCA's, one of whom provided cover for annual leave, a dispensing assistant and a delivery driver.

Team members used a range of questions to obtain relevant information before selling over-the-counter (OTC) medicines and if they were unsure, details were run past the RP. Sufficient knowledge of OTC medicines was held and demonstrated.

Ongoing training for the team was through literature that they received through the post, staff took instruction from the RP, they completed modules from Numark, CPPE and online e-learning modules to keep their knowledge current. Staff received formal appraisals annually with the RP where their progress was monitored and as they were a small team, they communicated verbally with regular discussions occurring between them.

There were no formal or commercial targets set to achieve services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are clean and adequate to provide services from.

Inspector's evidence

The premises consisted of a small sized retail area and a small dispensary. The latter was at the rear and consisted of about two to three metres by two metres. There was a central table in the dispensary, a small space by the sink/at the back and a front dispensing bench. The space by the sink was used to assemble MDS trays. There was limited space for dispensing processes to occur and for medicines to be stored appropriately, but this was adequate in line with the pharmacy's current volume of dispensing. The size of the dispensary also meant that not many people could be present at any one time.

There was a staff kitchenette area to one side of the retail space that was also being used as a stock room, this was cluttered and there were another two rooms to one side of the dispensary. One of the rooms stored dispensed prescriptions that were awaiting collection, the other space contained the pharmacy’s paperwork. Both rooms were adjoining, and the area was also accessible from behind the front counter. There was a sign on the door of this section that stated, ‘private consultation room’, although the RP explained that the staff kitchenette area was currently being used if private conversations were required or if services were provided. The unsuitability of this area due to the clutter and space constraints was discussed during the inspection. The RP was considering using the second room that contained paperwork and as people would need to pass through the room where dispensed prescriptions, awaiting collection were stored, storing these in a way that limited access to confidential information was discussed at the time.

The pharmacy was clean, suitably lit and well-ventilated. Areas that faced the public were presented appropriately and the pharmacy was professional in appearance. Pharmacy only (P) medicines were stored behind the front counter and staff were always within the vicinity, to help prevent them from being self-selected.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy obtains medicines from reputable sources and it stores most medicines appropriately. But, some of its medicines are held 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. In general, team members ensure that most of the pharmacy's services are provided safely and effectively. But, they don't always identify prescriptions that require extra advice or record relevant information. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. And, the pharmacy does not always provide medicine leaflets. This means that people may not have all the information they need to take their medicines safely.

Inspector's evidence

The pharmacy was accessible from the street and there was clear, open space inside the premises. This allowed easy entry for people with wheelchairs. The pharmacy's opening hours were listed on the front door and there were some shared car parking spaces with the adjacent GP surgery, located outside the pharmacy. There was one seat available for people waiting for prescriptions. The team described facing people who were partially deaf so that they could lip-read, staff provided one-to-one assistance for people who were visually impaired and verbally explained details. They also described using gestures to assist people whose first language was not English.

There were some leaflets available for people to access information about other local services and staff used online details as well as their own knowledge to help signpost people to other local organisations. The pharmacy team used baskets to hold each prescription and associated medicines. This prevented any inadvertent transfer from occurring. Staff used a dispensing audit trail to verify their involvement in processes, which was through a facility on generated labels. The ACT explained that when she accuracy-checked prescriptions, the RP generated labels and completed the clinical check at this point, he marked prescriptions with a 'CC' to indicate that this had occurred, and other staff were then involved with dispensing the prescriptions.

Staff were aware of risks associated with valproate as they had completed training about this through Numark. The RP was made aware if prescriptions were seen for females in the at risk group and he spoke to them to make them aware. There was also relevant literature available that could be provided upon supply if 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 stable and they were monitored at the GP surgery. 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.

Dispensed prescriptions awaiting collection were attached to bags. Staff could identify fridge items and CDs (Schedules 2-3) as these were highlighted. Schedule 4 CDs were not identified using any means and uncollected medicines were checked and removed every few months.

MDS trays were supplied to people who found managing their medicines difficult after the pharmacist liaised with the person's GP. Prescriptions were ordered by the pharmacy, when 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. Staff were in the process of creating individual records for each person who received trays. They ensured that clear dosing instructions were placed on generated labels and provided descriptions of medicines within trays. Trays were not left unsealed overnight and all medicines were de-blistered into trays with none left within their outer packaging. Mid-cycle changes involved trays being retrieved and new trays being supplied. The team only provided Patient Information Leaflets (PILs) periodically or with new medicines and although the team was aware of precautions associated with finasteride, they were unsure whether people, who received this medicine inside trays, had carers. This was discussed during the inspection.

The pharmacy provided a delivery service and it kept audit trails to demonstrate when and where medicines were delivered. This included identifying CDs and fridge items. People's signatures were obtained when they were in receipt of their medicines and the driver brought back failed deliveries. Notes were left to inform people about the attempt made and medicines were not left unattended.

Licensed wholesalers were used to obtain medicines and medical devices. This included Alliance Healthcare, Colorama, Sigma and AAH. Unlicensed medicines were obtained through Colorama. 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 he was in the process of implementing the SOP.

Medicines were date-checked for expiry every three months and a schedule was used to demonstrate the process. Short dated medicines were identified using stickers and there were no date-expired medicines seen. In general, CDs were stored under safe custody. The key to the cabinet was maintained in a manner that prevented unauthorised access during the day. Medicines were stored evenly and appropriately within the pharmacy fridge.

However, there were several medicines stored outside of their original containers that were not marked with all the relevant details, such as batch number and expiry dates. There were also loose blisters of medicines present on the dispensary shelves. Once accepted, the team stored returned medicines requiring disposal within appropriate receptacles. People bringing back sharps for disposal were referred to the GP surgery and CDs returned for destruction were brought to the attention of the RP. Relevant details were entered into a CD returns register.

Drug alerts were received by email and through wholesalers. The team checked for stock and acted as necessary and there was an audit trail available to verify the process.

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 and necessary equipment. This included counting triangles, an operating medical fridge, CD cabinet and one clean, crown-stamped conical measure for liquid medicines. Obtaining a second measure was discussed at the time, in case the first one broke.

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.