General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Porlock Pharmacy, Doverhay, Porlock, MINEHEAD, Somerset, TA24 8PT

Pharmacy reference: 1036332

Type of pharmacy: Community

Date of inspection: 23/05/2019

Pharmacy context

This is a community pharmacy located on the main High street in the village of Porlock in Somerset. A range of people use the pharmacy's services, and this includes a high proportion of the elderly and tourists. The pharmacy dispenses NHS and private prescriptions. It provides Medicine Use Reviews (MURs), emergency hormonal contraception and flu vaccinations during the season. And, it supplies some people with their medicines inside 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

In general, the pharmacy manages risks effectively. When things go wrong, team members deal with mistakes responsibly. But, they don't 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 organised, its work spaces were clear of clutter and the pharmacy's workload was manageable. Near misses were routinely seen recorded and a discussion with staff was held every week to review and to raise the team's awareness of trends or patterns seen. This included separating medicines that were similar in name or packaging, such as gabapentin and pregabalin. The review process was described as occurring informally and details were not documented to support the process.

There was information on display to inform people about the pharmacy's complaints procedure. The Responsible Pharmacist (RP) explained that his process for managing dispensing incidents or complaints involved apologising, checking relevant details, being polite and courteous, remedying the situation and informing the person's GP if anything was taken incorrectly. The RP also held a follow up conversation to inform the person about the outcome and to try and improve their confidence in the pharmacy's ability to provide services in the future. The RP stated that details about incidents were documented, this included recording information on people's records and reporting to the National Reporting and Learning System (NRLS). There was no information available about previous incidents and the RP stated that none had occurred for some time.

Staff were trained to identify signs of concern and were vigilant in safeguarding vulnerable people. They described using their own common sense, referred to the RP in the first instance and explained that they offered Monitored Dosage Systems if people were noted as becoming forgetful with their medicines or if they were concerned about some people, they delivered medicines to them so that they could keep an eye on them. Team members were trained through previous employment, from their own life experiences and from reading some relevant information. The team were also trained as dementia friends and described completing online training for this. The pharmacist was trained to level 2 via the Centre for Pharmacy Postgraduate Education (CPPE). Local contact details for safeguarding agencies were present and readily accessible.

Staff were trained on data protection and this included the European General Data Protection Regulation. They shredded confidential waste and ensured that there was no confidential material left in the retail space. The RP accessed Summary Care Records for emergency supplies and people's

consent was obtained verbally for this. Bagged prescriptions awaiting collection were stored in a location, where sensitive details were not visible from the retail space. However, the latter were stored in close vicinity to the stairs and there were some potential concerns with maintaining people's private information when the consultation room was used (see Principle 3).

There was a range of documented Standard Operating Procedures (SOPs) present that were recently implemented. Team members were described as being in the process of reading through the SOPs and signing them. The correct RP notice was on display and this provided details of the pharmacist at the time, who was in charge of operational activities. Records of emergency supplies and most records of private prescriptions were maintained in line with statutory requirements. Odd records for the latter were seen where prescriber details were only recorded as "dentist".

A sample of registers for Controlled Drugs (CD) were seen to be compliant with the Regulations. Balances for CDs were checked with every transaction and on randomly selecting CDs held in the cabinet (Zomorph, Shortec), their quantities matched the balance recorded in corresponding registers. Records for the receipt and destruction of CDs, brought back by people for disposal were maintained in full. There were missing entries seen in the electronic RP record, where pharmacists had failed to record the time that their responsibility ceased, and some relevant details were missing within records of unlicensed medicines. Professional indemnity insurance arrangements were provided through the National Pharmacy Association (NPA) and this was due for renewal after 31/12/19.

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. The pharmacy now ensures that all its team members are undertaking appropriate training for their roles. And, they complete ongoing training to help keep their skills and knowledge up to date.

Inspector's evidence

The pharmacy dispensed approximately 4,500 to 5,000 prescription items every month with 24 people receiving their medicines inside Monitored Dosage Systems (MDS). Staff present included the RP who was also the superintendent pharmacist for the company, a trained Medicines Counter Assistant (MCA) and two trained dispensing assistants. There was also another MCA. Staff covered each other as contingency for absence or annual leave and the MCA explained that she assisted in the dispensary when this occurred or when help was required. This member of staff had been employed by the pharmacy for the past five years and at the point of inspection, she had not completed or was not enrolled onto any accredited training to support this activity.

This was not in line with the GPhC's minimum training requirements which specifies that any assistant given delegated authority to carry out certain activities should have undertaken or be undertaking an accredited course relevant to their duties within three months of commencing their role. This situation and the risks associated was discussed at the time. Following the inspection, the RP provided email confirmation that both MCA's were subsequently enrolled onto the appropriate training with the NPA.

Counter staff asked a range of questions to determine suitability before selling medicines over the counter, they referred to the pharmacist when required and monitored people if they saw that excess requests for medicines prone to abuse were occurring. Sufficient knowledge of medicines was held.

Staff explained that because they were a small team, they could easily communicate verbally with one another and asked if they wanted to learn about anything new. Their progress was monitored informally but regularly and to assist with training needs, they took instruction from the RP, read relevant literature and completed online training various providers such as the CPPE. There were no formal targets set to achieve services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises are clean and appropriate to ensure the effective delivery of its services. But, people might see confidential information from inside and on their way to the consultation room. This means that the team may not always be keeping other people's private information safe.

Inspector's evidence

The pharmacy’s premises consisted of a medium sized retail area, a small dispensary located downstairs, another larger, space to dispense MDS trays and to hold some of the pharmacy’s stock was situated upstairs, along with an office and staff areas.

A consultation room was available to provide services and private conversations, but this was also situated upstairs. This meant that people had to walk into the dispensary and past bagged prescriptions, that were awaiting collection to climb the stairs before walking past bulkier assembled prescriptions that were stored outside the room. There were also baskets with prescriptions present inside the room. The RP explained that they were aware of issues with maintaining data protection, hence people were ushered into and out of the space and the room was cleared before use. The space was of a suitable size to provide services but there was no sign in the retail space, to indicate the presence of a room where private conversations could take place. The retail area was very well presented, the pharmacy’s fixtures and fittings were nostalgic which was in keeping with the history of the building and area. All areas were clean, and the pharmacy was suitably lit and well-ventilated.

Pharmacy only (P) medicines were, in the main stored behind the front counter although some (such as Pepto-Bismol products) were seen stored on shelves that extended past the front counter and this could have allowed these medicines to be self-selected by people. This was discussed at the time, staff explained that they were usually present, people were not known to usually help themselves to medicines as they always asked for assistance and the medicines were moved during the inspection.

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. And it stores some medicines 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 makes checks to ensure that the fridge used to store medicines is working properly. But, team members don't record details of the action taken when the temperature is outside the maximum range. So, they may not always be able to demonstrate that medicines have been appropriately stored. In general, team members ensure that most of the pharmacy's services are provided safely and effectively. But, members of the pharmacy team may be routinely ordering people's repeat prescriptions without them needing all the medicines. And, 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.

Inspector's evidence

The pharmacy could be accessed through a wide front door and a step. Staff physically attended people with wheelchairs or restricted mobility at the door and there were bars on one side of the entrance to help people to enter the pharmacy if needed. The team explained that they spoke slowly and/or provided written details to help communicate for people who were partially deaf, labels with a larger sized font were provided to people who were visually impaired, and staff physically assisted where possible. There was one seat available for people waiting for prescriptions and a pay and display car park located next to the pharmacy. The pharmacy's opening hours were listed on the front door and some leaflets about local services were also on display.

MDS trays were supplied to people after the GP assessed their suitability and the pharmacy was currently operating a waiting list. Prescriptions were ordered by the pharmacy, when received, details were cross-referenced against individual records to help identify changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. Descriptions of medicines within trays were provided and all medicines were de-blistered into trays with none left within their outer packaging. Patient Information Leaflets (PILs) were not routinely supplied but the dispensing assistant responsible for assembling trays explained that she was looking into asking people if this was required. This situation was discussed during the inspection. The pharmacy supplied finasteride inside trays for two people, staff were unsure whether they had carers but knew about the risks associated with this medicine. Mid-cycle changes involved retrieving the old trays and supplying new trays.

The pharmacy occasionally delivered medicines and the driver from the pharmacy's other local branch was used to assist with this. CDs were assembled when the driver arrived, and fridge items were marked onto prescriptions. Staff explained that the driver brought back failed deliveries to the pharmacy, they left notes to inform people of the attempt to deliver and medicines were not left unattended. At the point of inspection, there were no audit trails or records in place to verify when, where and to whom medicines were being delivered.

The GPhC's guidance on this situation was discussed at the time and following the inspection, the RP provided written confirmation by email that the record sheets used by the pharmacy's other branch

had subsequently been adopted to assist with this. The potential risk of access to confidential information from the way signatures were obtained and the layout used was also discussed during the inspection.

The pharmacy team used an in-house ordering system to obtain repeat prescriptions. This involved initially, setting up people's details by including all of their repeat medicines. Every month, the team then sent a copy of this to the person's GP surgery to generate repeat prescriptions for all the items without checking with the person what was required. The inspector was told that the GP surgery informed them if medicines had been stopped. On hand-out, the team asked people whether all the medicines were required and if anything was not, they marked the prescription as "not dispensed" before submitting for payment. The RP stated that written consent was obtained for each person who used the pharmacy's repeat ordering system.

Staff used baskets to hold each prescription and associated medicines during the dispensing process. This helped prevent the inadvertent transfer of items. The team used a dispensing audit trail through a facility on generated labels to identify that they were involved in this process.

Team members were aware of risks associated with valproate and a shelf-edge label was seen placed in front of stock as an additional alert. There were no females of child bearing potential seen or identified as having been supplied with this medicine, according to the team and relevant material to provide to people upon supply was present.

Prescriptions for people receiving higher risk medicines were not routinely marked as requiring pharmacist intervention or for counselling to occur. The RP explained that he was aware of each person's dose who received higher risk medicines from his pharmacy, if new prescriptions were seen, people were asked about relevant parameters, such as the International Normalised Ratio (INR) level for those people prescribed warfarin. People receiving repeat prescriptions were monitored by the GP surgery and were described as stable. There were no relevant checks made here and no details were documented.

Assembled prescriptions awaiting collection were marked with details if there were fridge items and CDs (Schedules 2-3). Schedule 4 CDs were not routinely identified. Uncollected prescriptions were checked every week and removed every month. The pharmacy used licensed wholesalers to obtain medicines and medical devices. This included Doncaster, Lexon, AAH and Alliance Healthcare. Unlicensed medicines were obtained through Lexon. Staff were informed of the European Falsified Medicines Directive (FMD) through the RP's instruction. The pharmacy was registered with SecurMed, but the system was not set up to comply with the process. At the point of inspection, there was no guidance information present to support the team.

Medicines were stored in an organised manner in the dispensary and were date-checked for expiry every few months. The record for this and schedule to support the process was in place. Medicines approaching expiry, were identified using stickers and liquid medicines with short stability were marked with the date they were opened. Some medicines were stored outside of their original containers without all relevant details recorded (batch number and expiry dates were missing). There were also some loose blisters of medicines seen upstairs and although medicines requiring cold storage were stored appropriately in the fridge, the pharmacy's records demonstrated that the temperature fluctuated outside the maximum range permitted and the team did not always mark the action taken in response to this. In general, CDs were stored under safe custody and keys to the cabinet were maintained in a manner that prevented unauthorised access during the day.

Medicines returned by the public for disposal were stored within appropriate receptacles. People

requesting sharps to be disposed of, were referred to the local council and staff provided them with a leaflet with this information. Returned CDs were brought to the attention of the RP. The pharmacy team received drug alerts by email, on receipt, they then checked for stock and acted as necessary. An audit trail was maintained 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

Current versions of reference sources were present. Computer terminals were password protected and positioned in a way that prevented unauthorised access. Staff used their own NHS smart cards to access electronic prescriptions and stored them appropriately overnight. A shredder was available to dispose of confidential waste.

There were clean, crown stamped conical measures for liquid medicines and counting triangles available. However, the latter needed cleaning. The sink used to reconstitute medicines was clean and there was hot and cold running water available as well as hand wash present.The fridge was maintained at appropriate temperatures for the storage of medicines.The CD cabinets were secured in line with legal requirements.

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.