General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Colyton Pharmacy Ltd, Colyton Pharmacy, Market Place, COLYTON, Devon, EX24 6JS

Pharmacy reference: 1030695

Type of pharmacy: Community

Date of inspection: 14/11/2019

Pharmacy context

This is a community pharmacy located in the centre of Colyton in Devon. The pharmacy dispenses NHS and private prescriptions. It offers some services such as Medicines Use Reviews (MURs), the New Medicine Service (NMS), seasonal flu vaccinations and minor ailments. The pharmacy provides multi-compartment compliance aids to people in their own homes if they find it difficult to manage their medicines. And, it supplies medicines to care homes.

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

Overall, the pharmacy operates in a satisfactory manner. Members of the pharmacy team understand the need to protect the welfare of vulnerable people. They deal with their mistakes responsibly. And, the pharmacy adequately maintains most of its records in accordance with the law. But, it does not formally review or record its internal mistakes or always record enough details for all its records. This makes it harder for team members to spot patterns and help prevent the same things happening again. And, they may not have enough information available if problems or queries arise in the future.

Inspector's evidence

The pharmacy held a range of documented standard operating procedures (SOPs) to support its services. They were from 2019, and they had been read and signed by the team. Staff understood their roles and responsibilities. However, an incorrect notice for the responsible pharmacist (RP) was initially on display. The inspection took place first thing in the morning, this was identified by the RP and subsequently changed so that it provided the correct details of the pharmacist in charge of operational activities on the day.

The pharmacy's workload was organised, and its activities took place from distinct areas. Repeat prescriptions and multi-compartment compliance aids were processed in the second and back part of the dispensary. This area could not be seen from the retail space which helped reduce distractions. There were designated members of the team responsible for undertaking these processes. Medicines for the care homes were assembled and compliance aids were stored on the first floor. Repeat prescriptions were dispensed for people and stock was unpacked at the back of the first half of the dispensary, with prescriptions for people who were waiting, being processed at the front of this section. The RP also worked from a designated area in this half of the dispensary to accuracy-check prescriptions.

Staff described unusual formulations being highlighted on prescriptions, medicines with different pack sizes were identified and caution notes were placed in front of stock as an additional visual alert to help prevent errors. The inspector was told by some members of the team that near misses were discussed at the time, medicines that were similar were highlighted but details were not recorded. A near miss log was seen where details had been recorded by the RP. However, the details had been sporadically documented and there were gaps where information about the action taken in response or learning had not been recorded. Although an annual patient safety report from 2018 was seen completed and previous monthly patient safety reports from 2018 were present, there was limited evidence that internal errors were being routinely recorded and reviewed. This reduced the ability of the pharmacy to demonstrate that patterns and trends were being identified, acted upon and learnt from.

There was a documented complaints process in place and incidents were handled by pharmacists. Their process was in line with the policy and included checking details, apologising, assessing the level of harm, providing additional details about where to escalate if required, recording details and rectifying the situation. Previous details of documented incidents were seen, and the pharmacy reported them to the National reporting and Learning System (NRLS). However, there were no details on display to inform people about the pharmacy's complaints procedure. This meant that people may not have been able to raise their concerns easily.

Staff could identify signs of concern to safeguard the welfare of vulnerable people and referred to the RP in the event of a concern. This included the delivery driver. The RP was trained to level two via the Centre for Pharmacy Postgraduate Education. There were relevant contact details about the local safeguarding agencies available within the signposting document. The SOP to provide the team with guidance was initially missing but implemented immediately after the inspection. There was no confidential material left within areas that faced the public. Staff segregated confidential waste before it was shredded and sensitive details on dispensed prescriptions awaiting collection could not be seen from the retail space. Summary Care Records had been accessed for queries and consent had been obtained verbally from people for this. However, there was no information on display about how the pharmacy maintained people's privacy.

The pharmacy's indemnity insurance was through the National Pharmacy Association and due for renewal after 31 July 2020. Records for the maximum and minimum temperatures for the pharmacy fridge were kept daily to verify that medicines were stored within the correct temperature range. There were occasional issues seen with the pharmacy's records that it was obliged to routinely keep. This included occasional over-written or crossed out entries that had not been appropriately annotated within a sample of registers seen for controlled drugs (CDs), previous records of unlicensed medicines were routinely maintained in line with statutory requirements, but some recent records had prescriber details missing, there were occasional missing dates within records of private prescriptions and the nature of the emergency was missing occasionally for records of emergency supplies. The RP record was largely complete.

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 are provided with training resources to help improve their skills and knowledge.

Inspector's evidence

Staff present during the inspection included the RP who was also the superintendent pharmacist, three trained dispensing assistants and a medicines counter assistant (MCA). The team's certificates of qualifications obtained were seen. Team members covered each other as contingency, they held set roles and understood their tasks. Counter staff asked relevant questions before selling over-the-counter (OTC) medicines. They referred to the RP when they were unsure or when required. Unusual quantities or requests of some medicines with potential for abuse were monitored, and subsequent sales were referred to the RP and the person's GP. As the pharmacy provided services to a local community, staff were observed taking their time with each person to help resolve their queries and a positive rapport was observed. To assist with training needs, the team completed training modules from Numark and took instructions from pharmacists. They communicated verbally as they were a small team and staff progress was described as being monitored informally but regularly by the RP. There were no formal targets in place to complete services.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide an appropriate environment to deliver healthcare services. The pharmacy is clean, and it has a space to offer private conversations and services

Inspector's evidence

The pharmacy premises consisted of a medium sized retail area and dispensary that was made up of two areas. There was enough space for the pharmacy’s processes to take place safely with significant space upstairs. The latter included storage, staff and stock areas as well as unused parts. The pharmacy was suitably lit, was appropriately ventilated and presented appropriately. Pharmacy (P) medicines were stored behind the front counter, staff were always within the vicinity and this helped restrict P medicines from being self-selected. There was no barrier to prevent people from walking into the dispensary, staff stated that if people occasionally stood or came into this area, they asked them to step back. The consultation room was signposted and used for private conversations and services. The entrance from the retail space was kept locked, the size of the room was adequate for its intended purpose and there was no confidential information present.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy largely provides its services in a safe manner. Its team is helpful and tries to ensure everyone can access the pharmacy's services. The pharmacy obtains its medicines from reputable sources. It generally manages and stores them appropriately. Although team members identify most prescriptions that require extra advice, they don't always record enough information. This makes it difficult for them to show that appropriate advice has been provided when these medicines are supplied. And, the pharmacy doesn't always maintain records of the services that it provides. This could mean that it may not have enough information available if problems or queries arise in the future.

Inspector's evidence

People could enter the pharmacy through a wide front door at street level and there were wide aisles and clear, open space inside the premises. This helped people with restricted mobility or wheelchairs to easily access the pharmacy's services. Staff described taking their time with people who had different needs and subsequently adjusting accordingly. This included carrying people's shopping to the car for them, monitoring people and noticing if they required additional help, facing people who were partially deaf so that they could lip-read and using the consultation room. The pharmacist could also speak Spanish if required. There was one seat available for people waiting for prescriptions. The pharmacy's opening hours were on display. Staff could signpost people to other services from their own knowledge and from the documented details that were present.

The pharmacy was healthy living accredited and held the national campaigns to educate people on relevant topics. Some discussions had been held with people, according to the team on healthier lifestyles, people had taken the available literature and they had referred people in the past to other providers of health. The pharmacy also provided an influenza vaccination service and carried out risk assessments, informed people's GP's and obtained informed consent before commencing the service. The Patient Group Directions (PGDs) to authorise the service were readily accessible and had been signed by the RP, the pharmacist's declaration of competence was seen, he was trained through accredited routes and there was relevant equipment present. This included a sharps bin and adrenaline, required in the event of a life-threatening allergic reaction to vaccines. However, the PGDs for the minor ailment services present had expired and some supplies had taken place after this. Once highlighted, this was immediately remedied by the RP and the relevant PGDs implemented.

Compliance aids: People were supplied with compliance aids in their own homes after the GP initiated them. Prescriptions were received directly from the surgery, staff monitored when they were due and when received, the team cross-referenced details against people's individual records or records on the pharmacy system to identify any changes or missing items. This was confirmed with the prescriber and records were maintained. Summaries of when people had been discharged from hospital were also retained and the team monitored when prescriptions were due. All medicines were de-blistered into the compliance aids with none left within their outer packaging. Descriptions of medicines were provided, patient information leaflets (PILs) were routinely supplied and the compliance aids were not left unsealed overnight. Mid-cycle changes involved retrieving, amending, re-checking and re-supplying them.

Care homes: The pharmacy provided medicines to the care homes as compliance aids against batch

prescriptions or repeat dispensing. Medicines that were on a 'when required' basis were ordered directly by the homes. Interim or mid-cycle items were dispensed at the pharmacy. PILs were routinely supplied to the homes. The RP had been approached to provide advice regarding covert administration of medicines to care home residents. He had used relevant reference sources and alternative formulations, or medicines had been sought. However, there had been no details documented that could help verify this process.

Deliveries: The pharmacy delivered medicines to people's homes, it used an app to manage this and records were maintained to help verify the process. Fridge items and CDs were identified, and signatures were obtained from people when they were in receipt of their medicines. Failed deliveries were brought back to the pharmacy and notes were left to inform people about the attempt made. Medicines were sometimes left with a neighbour provided permission had been obtained to do this. The driver had read the pharmacy's SOP on the process and had shadowed another driver as part of his initial training. The driver was also aware of signs that could indicate a safeguarding concern, he had referred to the RP and provided several examples of when this had happened previously. This included helping vulnerable people when they had fallen and calling home help for them when needed. In addition, the pharmacy delivered mobile equipment (such as commodes or frames) to people under a locally commissioned scheme, this was initiated by the local occupational therapy team who were responsible for training people on how to use them. However, the driver also assisted and provided explanations where possible, when required.

The pharmacy provided a repeat prescription ordering system where people's repeat slips were retained, staff were called when prescriptions were required, or they ordered the items for people on their behalf every four weeks, sent them to the surgery and monitored their return. However, there were no audit trails being kept verifying this process.

Staff were aware of the risks associated with valproates, and there was literature available to provide to females at risk, upon supply of this medicine. People prescribed higher-risk medicines who collected their medicines from the pharmacy were routinely identified and asked about relevant parameters. This included asking about the International Normalised Ratio (INR) level for people prescribed warfarin. However, this process did not take place for residents in the care homes, for people receiving compliance aids or deliveries and there had been no details recorded to verify that appropriate checks were being made.

The team used baskets to hold prescriptions and medicines to prevent any inadvertent transfer. Staff involvement in dispensing processes was apparent through the dispensing audit trail that was used. This was through a facility on generated labels. Once prescriptions were assembled, they were attached to bags. Fridge items and CDs were identified. Uncollected medicines were removed every month.

The pharmacy obtained its medicines and medical devices from licensed wholesalers such as Alliance Healthcare, AAH, Phoenix and OTC Direct. Alliance or Colorama were used to obtain unlicensed medicines. The pharmacy was not yet complying with the European Falsified Medicines Directive (FMD) and staff were unaware of and not yet trained on the decommissioning process. Medicines were stored in an organised manner. The team date-checked medicines for expiry every few weeks and used a schedule to help verify this. There were no date-expired medicines or mixed batches seen although occasionally poorly labelled containers were present. Short-dated medicines were identified. Liquid medicines with short stability, were generally marked with the date upon which they were opened. CDs were stored under safe custody. Keys to the cabinet were maintained during the day and overnight in a manner that prevented unauthorised access. Drug alerts were received by email or through wholesalers, stock was checked, and action taken as necessary. An audit trail was available to verify this

process. However, the safety alerts were not routinely passed to the homes to check for affected stock.

The pharmacy used designated containers to hold medicines returned by people for disposal. They were collected in line with the pharmacy's contractual arrangements and included containers for hazardous or cytotoxic medicines as well as a list for the team to identify these medicines. People returning sharps for disposal were referred to the local council. Returned CDs were brought to the attention of the RP, details were noted, they were segregated and stored in the CD cabinet prior to destruction.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services safely. The pharmacy uses its facilities appropriately to protect people's privacy.

Inspector's evidence

The pharmacy was equipped with current reference sources and the team could contact the NPA's information services for advice and support if required. Relevant equipment included counting triangles and a range of standardised, conical measures for liquid medicines. The dispensary sink used to reconstitute medicines was relatively clean. There was hot and cold running water available with hand wash present. The CD cabinet was secure. Medicines requiring cold storage were stored at appropriate temperatures within the fridge. Computer terminals in the dispensary were positioned in a manner that prevented unauthorised access and staff could use cordless phones to help conversations to take place in private. A shredder was available to dispose of confidential waste. Team members used their own NHS smart cards to access electronic prescriptions and took them home overnight.

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.