General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Downley Pharmacy, 9 Cross Court, Plomer Green Avenue, Downley, HIGH WYCOMBE, Buckinghamshire, HP13 5UW

Pharmacy reference: 1112308

Type of pharmacy: Community

Date of inspection: 05/12/2019

Pharmacy context

This is a community pharmacy located amongst a parade of shops in the village of Downley, near High Wycombe in Buckinghamshire. The pharmacy dispenses NHS and private prescriptions. It offers a few services such as Medicines Use Reviews (MURs), seasonal flu vaccinations and delivers medicines. The pharmacy also provides multi-compartment compliance aids to people if they find it difficult to manage their medicines. And, it operates a collection point where people can collect their medicines outside of the pharmacy's opening hours.

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 identifies and manages risks appropriately. The pharmacy's team members protect the welfare of vulnerable people and people's privacy well. The pharmacy generally maintains its records in accordance with the law. Members of the pharmacy team monitor the safety of their services by recording their mistakes and learning from them.

Inspector's evidence

The pharmacy was organised, and this included the way its stock was stored. There was a range of documented standard operating procedures (SOPs) present to support the pharmacy's services. They were from 2018 and the pharmacy team's roles and responsibilities were defined within them. However, only two members of staff had read and signed them. This was described as work in progress but could mean that staff were unclear on the pharmacy's current processes to follow. Overall though team members understood their roles and responsibilities and knew the activities that were permissible in the absence of the responsible pharmacist (RP). The correct RP notice was on display and this provided people with the details of the pharmacist in charge of operational activities on the day.

A book was used to record details of the team's near misses and comprehensive records were maintained. Trends had been seen where medicines that were similar in name and packaging were incorrectly selected such as amitriptyline and amlodipine as well as different strengths of atenolol and citalopram. They were highlighted to the team and when medicines were supplied to people, staff made them aware of any similarities to help highlight risks. They identified and highlighted people with similar names on the pharmacy's system to help minimise mistakes happening and had created bespoke stickers for 'mixed batches' to make people aware that some of their medicines may have come from different batches. Staff explained that as part of the review process, a discussion took place every month, they recalled being asked to slow down, mistakes had happened because they were rushing and in response, people's waiting times had been increased to help make the pharmacy's processes safer. However, there were no details seen recorded about this. This limited the ability of the team to verify that trends and patterns were being identified and remedial activity undertaken in response.

The RP handled incidents, her process was in line with the pharmacy's documented complaints process and included apologising, rectifying the situation and recording details. However, at the point of inspection, there were no details on display about the pharmacy's complaints procedure. This could mean that people may not have been able to raise their concerns easily.

Staff ensured that no confidential material was left in the retail space. They used the consultation room for private conversations, lowered their voices when they were working and had signed confidentiality statements. The pharmacy held guidance information for the team about information governance. There was information on display to inform people about how their privacy was maintained. Confidential waste was segregated before it was disposed of through an authorised carrier. Dispensed prescriptions awaiting collection were stored in a location where sensitive information could not be seen. Summary Care Records had been accessed for emergency supplies or queries and consent was obtained in writing as well as verbally from people for this.

The team could identify signs of concern to safeguard the welfare of vulnerable people, this included the delivery driver and staff were trained as dementia friends. They informed the RP in the event of a concern and the driver described a previous incident. The pharmacist had been trained to level 2 through the Centre for Postgraduate Pharmacy Education (CPPE) as well as through her work with the local Scouts. The former was due for renewal. There were relevant contact details for the local safeguarding agencies and the pharmacy's chaperone policy was on display.

Most of the pharmacy's records relating to its services were compliant with statutory requirements. This included records of unlicensed medicines, the RP record and a sample of registers seen for controlled drugs (CDs). On randomly selecting CDs held in the cabinet, their quantities matched the balances that were recorded in the corresponding registers. Balances for CDs were checked every month. The maximum and minimum temperatures for the fridge were checked every day and records were maintained to verify that they remained within the required temperature range. Staff kept a complete record of CDs that had been returned by people and destroyed at the pharmacy. The pharmacy's professional indemnity insurance arrangements were through Numark and this was due for renewal after 17 June 2020. There was only one date recorded for recent records of private prescriptions. This was discussed at the time.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload safely. Members of the pharmacy team are suitably qualified. They understand their roles and responsibilities. And, they are provided with resources to complete regular, ongoing training. This helps to keep their skills and knowledge up to date.

Inspector's evidence

The pharmacy was appropriately staffed during the inspection. Staff present at the time included the regular RP who was also the pharmacy manager, a pharmacy technician and two trained dispensing assistants. One of the dispensing assistants was trained as a medicines counter assistant (MCA) and the other was undertaking accredited training for this role. Staff covered each other as contingency and the team had the confidence to raise any concerns they might have had. Staff asked a range of appropriate questions before selling medicines over the counter and they referred appropriately to the RP. Staff in training completed course material at work as and when it was possible, they were managing to complete their course material in a timely manner. To assist staff with their training needs, staff had access to resources from Numark and CPPE, they used trade publications, read promotional material as well as regularly taking instruction from the RP. This helped to improve and keep their knowledge up to date. Staff progress was monitored informally and periodically by the RP. As they were a small team, team members communicated verbally with one another and used a notebook. There were a few targets in place to complete services. This included completing 250 MURs in the year. This was described as manageable and not an unrealistic target.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises generally provide a suitable environment to deliver its services. The pharmacy is clean and has a separate space for private conversations and services.

Inspector's evidence

The pharmacy premises consisted of a small to medium sized retail area and a somewhat larger, open plan dispensary behind. There was also additional space at the very rear which contained stock and staff facilities. The pharmacy was generally clean although the staff WC could have been cleaner. It was bright, appropriately ventilated and well presented. There was plenty of space in the dispensary with an island in the centre. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity to help prevent these medicines from being self-selected. Some bulky dispensed bags were stored directly on the floor in one corner of the dispensary, whilst they were out of the way and not a trip hazard, there was still a potential risk that medicines could be stepped on and damaged. Moving them off the floor was discussed during the inspection.

A signposted consultation room was available for services and private conversations. The room was spacious and of a suitable size for its intended purpose. The entrance was located close to the front counter and it was kept open. However, the room contained a sharps bin which meant that unauthorised access and a risk of needle-stick injury was possible. In addition, there was a fridge at the back of the room where influenza vaccinations (prescription-only medicines) were stored. This meant that unauthorised access to these medicines may have been possible. This was discussed with the RP at the time, the room was closed but could not be locked. Keeping this room locked, the sharps bin stored away appropriately and, or the fridge locked would help mitigate this risk.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy usually provides its services safely and effectively. Its services are easily accessible to everyone. The pharmacy obtains its medicines from reputable sources, it stores and manages them well. Team members identify prescriptions that require extra advice. But they don't always record enough information when people receive higher-risk medicines. This makes it difficult for them to show that they provide appropriate advice when these medicines are supplied.

Inspector's evidence

The pharmacy's opening hours and services that it provided were listed on the front door. People could enter the pharmacy from the street as well as through a wide, front door and as the retail space consisted of clear, open space, this helped people with wheelchairs or restricted mobility to easily use the pharmacy's services. Staff described using written details for people who were partially deaf or the consultation room to help reduce background noise. Physical assistance or details were provided verbally for people who were partially deaf, and representatives or gestures were used for people whose first language was not English. There were two seats available for people waiting for prescriptions and car parking spaces outside.

The pharmacy displayed some leaflets that provided information about other local services. There was documented information present that staff could use alongside their own knowledge of the area or online resources, to signpost people to other local organisations. Staff described referring people to smoking cessation and mental health services. They were currently asking people with diabetes about foot and eye checks. The RP regularly wrote and provided articles about seasonal topics in the local parish magazine. This had included providing advice about inhalers and certain conditions such as Reye's Syndrome. The team had also set up a stand at the local village fete to provide advice about inhaler techniques and monitor people's blood pressure.

The RP described the influenza vaccination service as being very popular with the local population due to the convenience of the pharmacy setting and ease of access to the service. This service was provided on a walk-in basis. The RP had completed appropriate training and there was suitable equipment to safely provide the service. This included adrenaline in the event of a severe reaction to the vaccines. The Patient Group Directions (PGDs) to authorise this service were readily accessible and had been signed by the RP. This also included the service specification. Risk assessments were completed before vaccinating, informed consent was obtained and patient information leaflets (PILs) provided. Once people were vaccinated, their GP was also informed.

The pharmacy also provided an automated collection point. Dispensed prescriptions were stored inside and could be collected from a vending machine. This could be accessed by people 24 hours a day and on seven days of the week. The machine was located to one side of the premises, with the internal section accessible from the consultation room. The pharmacy had deregistered the area in which the vending machine was situated, so that an RP and their supervision was not required. This meant that the vending machine could then operate outside the pharmacy's opening hours. This service had been set up at the beginning of 2019, the pharmacy had obtained written consent from people to sign up to the service and there was an SOP to provide guidance to the team. There was also a quick reference guide for the team. Prescriptions for CDs, fridge and bulky items were not included as part of the

service. The RP described calling people beforehand if counselling was required, or people were texted and, or notes placed inside dispensed bags asking people to call them. This included prescriptions with higher-risk medicines or where pharmacist intervention was required.

Once people had signed up to the service and the machine had been loaded by staff, people received a unique pin to enter into the machine when they came to collect their prescription. This was sent via email through the person's medication record and by text message by staff. Due to the risk of human error for the latter, staff explained that they triple checked details before codes were sent, they maintained records of the details entered and sent by text, checked that the text had been received as well as audited the system. According to the team, there had been some uptake of the service, this was convenient for people who worked longer hours or could not access the pharmacy's services during their opening hours and it was still being trialled by the company.

The pharmacy delivered dispensed prescriptions to people. There were records available to demonstrate when this had taken place and to whom medicines were supplied. Signatures from people were obtained once 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 to deliver. Medicines were not left unattended unless permission was obtained. This included for example using a key safe number, relevant risks such as pets and children were checked and people were asked to phone the pharmacy to confirm that they had received their medicines.

The pharmacist assessed people's suitability for multi-compartment compliance aids, alternatives were offered if they were unsuitable along with explanations or the team labelled people's medicines differently to help them take their medicines as prescribed. Once compliance aids were set up, staff ordered prescriptions for people on their behalf. When received, they cross-referenced details against individual records to help identify any changes or missing items. The team checked queries with the prescriber and maintained records to verify this. All medicines were de-blistered and removed from their outer packaging before being placed into the compliance aids. Compliance aids were not left unsealed overnight and patient information leaflets (PILs) were routinely supplied. Mid-cycle changes involved either retrieving the compliance aids, amending them, re-checking and re-supplying them or supplying new compliance aids. However, the pharmacy team did not always provide descriptions of medicines supplied within the compliance aids.

Staff were aware of risks associated with valproates, they identified females at risk before supplying this medicine so that they could be appropriately counselled. There was relevant literature available to provide to people, if required. This also included literature and booklets for people receiving other higher-risk medicines. For the latter, the team routinely asked about relevant parameters such as blood test results. This included asking about the International Normalised Ratio (INR) level for people prescribed warfarin. However, although this information was recorded for people with multi-compartment compliance aids, staff did not routinely keep records otherwise. This limited their ability to verify that the appropriate checks had been made.

During the dispensing process, staff used baskets to keep prescriptions and medicines separate. The baskets were also colour co-ordinated to help highlight priority. A dispensing audit trail through a facility on generated labels helped to identify staff involvement in processes. Dispensed prescriptions were stored with prescriptions attached. Fridge items and Schedule 3 CDs were identified. Schedule 2 CDs were assembled when people arrived to collect them and uncollected prescriptions were checked and removed every month.

The pharmacy obtained its medicines and medical devices from licensed wholesalers such as Phoenix,

AAH, Alliance Healthcare and Colorama. Staff were aware of the process involved with the European Falsified Medicines Directive (FMD). The pharmacy was registered with SecurMed, there were scanners present and guidance information for the team, but the pharmacy was not yet complying with the decommissioning process.

Medicines were stored on shelves in an ordered manner. The team date-checked medicines for expiry every three months and kept records to verify that the process had taken place. Medicines approaching expiry were highlighted. 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. Drug alerts were received via email, the process involved checking for stock and taking appropriate action as necessary. There were records present to verify this.

Medicines returned by people for disposal were stored within designated containers prior to their collection. There was also a list available for staff to identify hazardous and cytotoxic medicines. People returning sharps for disposal were referred to the local council for collection. Relevant details were taken about returned CDs and they were brought to the attention of the RP before being appropriately stored and destroyed.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

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

Inspector's evidence

The pharmacy was equipped with current versions of reference sources and clean equipment. This included crown-stamped conical measures for liquid medicines, counting triangles and the dispensary sink that was used to reconstitute medicines. There was hot and cold running water with hand wash available. The CD cabinet was secured in line with legal requirements. The blood pressure machine had been replaced in the past 18 months. Computer terminals were positioned in a manner that prevented unauthorised access. Staff held their own NHS smart cards to access electronic prescriptions and took them home overnight. Cordless phones were available to help conversations take place in private.

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.