General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Springvale Pharmacy, 18 Fraser Road, Kings Worthy, WINCHESTER, Hampshire, SO23 7PJ

Pharmacy reference: 1092591

Type of pharmacy: Community

Date of inspection: 19/09/2019

Pharmacy context

This is a community pharmacy located on a parade of shops in the village of Kings Worthy near Winchester in Hampshire. The pharmacy dispenses NHS and private prescriptions. It provides a range of over-the-counter (OTC) medicines, delivers medicines to people's homes and can measure people's blood pressure. The pharmacy supplies multi-compartment compliance aids to people if they find it difficult to manage their medicines. And, it provides medicines to a care home.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 not all met	1.1	Standard not met	The pharmacy is not identifying and managing several risks associated with its services as failed under the relevant principles. Most of the pharmacy's standard operating procedures (SOPs) are missing, they have not been kept at the pharmacy and there is no evidence that the team has read the SOPs
		1.2	Standard not met	There is not enough assurance that the pharmacy has a robust process in place to identify, manage and learn from dispensing incidents. Staff are not routinely recording near misses, records of dispensing incidents could not be located and there is limited evidence of remedial activity or learning occurring in response to mistakes
		1.3	Standard not met	Pharmacy services are not provided by staff with clearly defined roles and clear lines of accountability. There are limited audit trails in place to identify who was involved in dispensing, the roles and responsibilities of staff are not clearly documented, the pharmacy's SOPs do not make it clear where responsibility lies for different pharmacy activities
		1.4	Standard not met	There are limited systems in place to deal with complaints or feedback. The pharmacy does not provide people with information about how they can complain and there is no documented complaints procedure in place
		1.6	Standard not met	The pharmacy's records are not always maintained in line with legal requirements. This includes the record for the responsible pharmacist and records of supplies made against private prescriptions. In addition, all necessary records to verify that pharmacy services are provided safely should be readily available for inspection. The pharmacy has been unable to locate and show records of unlicensed medicines and controlled drugs, it therefore cannot demonstrate that it is making these supplies and records in line with the current legislation

Principle	Principle finding	Exception standard reference	Notable practice	Why
		1.8	Standard not met	The pharmacy does not have any processes in place to safeguard the welfare of vulnerable people
2. Staff	Standards not all met	2.2	Standard not met	Not all of the staff have the appropriate skills and qualifications for their role and the tasks they carry out. The pharmacy has not provided enough reassurance that the GPhC's minimum training requirements for the team are met and members of the pharmacy team are undertaking tasks without being enrolled on accredited training appropriate for this. This includes the owner's wife
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy has no processes in place for people prescribed higher-risk medicines, they are not being identified, counselled, relevant parameters checked, or details documented. The team prepares multi-compartment compliance aids and routinely leaves them unsealed overnight. They do not supply medicines information leaflets routinely with the compliance aids. This means that people may not have all the information they need to take their medicines safely. In addition, the pharmacy is not effectively managing the situation with medicines that are owed or signposting people to other providers when this happens
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance **Standards not all met**

Summary findings

The pharmacy doesn't always effectively manage risks associated with its services. It has written instructions to help with this. But, most of them are missing. And, members of the pharmacy team are unable to show that they have read them. This could mean that they are unclear on the pharmacy's current processes. Pharmacy team members are not always recording or formally reviewing their mistakes. This could mean that they may be missing opportunities to spot patterns, learn from them and prevent similar mistakes happening again. Team members understand how to protect the welfare of vulnerable people. But, there are no procedures in place to guide them. So, they may not know how to respond to concerns appropriately. They do understand how to protect people's private information. The pharmacy has not been able to show that it is maintaining all of its records, in accordance with the law.

Inspector's evidence

The inspection took place after mid-day. The responsible pharmacist (RP) and owner spent most of the inspection in the back office making telephone calls for the business, but the inspector did speak to him before the inspection commenced. Most of the dispensary's workspace was taken up with baskets of prescriptions waiting to be assembled and there were two to three piles of prescriptions dated from the 17 September 2019 that had been processed and required dispensing (see Principle 4). There were also untrained staff present (see Principle 2) and some of the pharmacy's paperwork or records had been taken home by the RP or could not be located (see below).

The workflow involved batch processing and dispensing prescriptions. There were separate areas for the pharmacist to conduct the final accuracy-check and for staff to assemble prescriptions. Staff described the RP holding a discussion with them when he identified a near miss, which helped to raise their awareness about the situation. An example provided included candesartan and losartan being interchanged due to similar packaging. However, other than very dated records (from 2011) there were no records of near misses or any information to confirm the action taken in response to errors. There was no information on display about the pharmacy's complaints process, no documented complaints process present or details about any previous incidents. Staff could not explain what the process was when mistakes happened and were unable to provide examples about the action that the pharmacy had taken in response.

A few documented standard operating procedures (SOPs) were present about some of the pharmacy's services such as the process for the RP's absence, fridge temperature recording, the delivery service and a few about dispensing processes. The SOPs seen were reviewed in 2018. However, only one member of staff had signed them, their roles and responsibilities were not always defined within them and there were several SOPs missing. The latter included the process for near misses and incidents, dispensing for the care home, dispensing of multi-compartment compliance aids, safeguarding and guidance on the management of people prescribed higher-risk medicines. The owner's wife stated that the RP had taken the rest of the SOPs home to be updated.

Staff could identify groups of vulnerable people who required safeguarding, they would inform the RP in the event of a concern and described knowing this information from the pharmacist. The inspector was told by the owner's wife that the RP had not updated his training on safeguarding for some years.

There was no SOP present, local policy information or contact details for the safeguarding agencies and staff were unaware of these, that an agency existed or where to locate the details. There was no chaperone policy seen.

The team segregated confidential waste before it was shredded and dispensed prescriptions awaiting collection were stored in a location that prevented sensitive information being visible from the retail area. There was no confidential information present in areas that were accessible to the public. However, there was no information on display to inform people about how their privacy was maintained, and no information governance policy seen to provide guidance to the team. One person's NHS smart card to access electronic prescriptions was left within a computer terminal and was being used by the team. This member of staff was not on the premises at the time, staff stated that their password was not known. Storing NHS smart cards securely overnight was advised during the inspection.

The pharmacy was indemnified through the National Pharmacy Association (NPA) and this was due for renewal after 31 August 2020. The team checked the minimum and maximum temperatures of the fridge to ensure medicines were appropriately stored here. Daily records were kept verifying this. Records of emergency supplies were recorded in line with statutory requirements.

However, the RP had taken the registers for controlled drugs (CDs) home. There was no appropriate or justifiable reason for this. Records of unlicensed medicines could not be located during the inspection. All necessary records for the safe provision of pharmacy services should be readily available for inspection. As the CD registers or records of unlicensed medicines were not available at the time of inspection, it has not been possible to determine whether the pharmacy is making these supplies in accordance with current legislation. There were also sustained, and consistent omissions seen in the electronic RP record where the pharmacist had not recorded the time that their responsibility finished. There were incomplete and missing prescriber details in the electronic private prescription register where the entry was either recorded as 'Private' only or only the postcode had been recorded.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy has enough staff to manage its workload safely. But, some members of the team are carrying out tasks that they are not trained for or qualified in. This increases the risk of things going wrong. It can affect how well the pharmacy cares for people and the advice that it gives. And, once team members have completed basic training, the pharmacy does not provide them with many resources or training materials to help keep their knowledge and skills up to date.

Inspector's evidence

Staff present during the inspection consisted of the RP who was also the superintendent pharmacist and owner, the owner's wife as well as two dispensing assistants. Other staff included the delivery driver and another dispensing assistant who was described as enrolled onto accredited training with the NPA.

One of the two dispensing assistants who were present was trained as a medicines counter assistant (MCA) and stated that she was enrolled onto accredited training for dispensing with the NPA. Course material was completed at home or at work. This member of staff was observed working on both the counter and dispensing during the inspection. The inspector was told by the other dispensing member of staff that he was not undertaking any formal training and he had worked at the pharmacy for the past four or five years. The owner's wife said that she completed administration and paperwork for the pharmacy, however, during the inspection, she was observed to sell a Pharmacy (P) medicine by asking very limited questions and there was no supervision or checks made with the RP before this medicine was sold. The owner's wife was not enrolled onto any accredited training that would support this activity in line with the GPhC's minimum training requirements. There was no evidence of enrolment seen for any staff member or certificates of qualifications obtained.

Staff working in a dispensing capacity were generally knowledgeable about their roles. The trained MCA asked relevant questions before OTC medicines were sold, knowledge of OTC medicines was demonstrated, and she referred to the RP appropriately if required. There were few resources available to assist staff with training needs. The inspector was told that the RP instructed them on relevant information. Staff progress was described as being monitored informally and because they were a small and close team, they discussed details verbally.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are clean. There is enough space to deliver services safely. And, the pharmacy can be secured to prevent unauthorised access.

Inspector's evidence

The pharmacy's premises consisted of a small to medium sized retail space with a dispensary located behind and a small office at the rear where multi-compartment compliance aids were dispensed and stored. There was enough space for dispensing processes to be carried out safely although much of the dispensing workspace was taken up with baskets of prescriptions. The pharmacy was appropriately presented, clean, suitably lit and ventilated. P medicines were stored behind the front counter and staff were always within the vicinity. This helped to prevent the self-selection of these medicines. There was a notice on display that alerted people that only members of staff could enter the dispensary.

A signposted consultation room was available to provide services and private conversations. The space was of an appropriate size for this purpose. However, the room was packed full of stock, boxes and medicines for the care home that were due to be delivered. This meant that there was no space here for people or the pharmacy team to use this room for its intended purpose. There were two entrances into the room, one was from the dispensary and the other from the retail space and although the latter was unlocked, it was inaccessible due to the presence of boxes stored in front of the entrance. Staff explained that if people wanted a private conversation, the RP took them to one side and a quiet area of the pharmacy for this.

Principle 4 - Services **Standards not all met**

Summary findings

In general, the pharmacy team is helpful and tries to ensure that people with different needs can easily access the pharmacy's services. The pharmacy obtains its medicines from reputable sources, it largely manages and stores them appropriately. And, the pharmacy makes some checks to ensure that medicines are not supplied beyond their expiry date. But, it has no up-to-date written details to confirm this. Whilst the pharmacy mostly provides its services in a safe manner, there are some areas that require further consideration. Team members don't always identify prescriptions that require extra advice. And, the pharmacy does not always provide medicines leaflets. This makes it difficult for them to show that appropriate advice has been provided or that people have all the information they need to take their medicines safely. The pharmacy's team members sometimes fill compliance aids then leave them unsealed overnight while they wait for them to be checked. This adds extra risk to the process.

Inspector's evidence

The pharmacy could be accessed from the street and through an automatic door. This, along with the wide aisles inside the premises and clear, open space meant that people needing wheelchair access could easily use the pharmacy's services. Staff had printed labels with a larger sized font for people who were visually impaired, they used written communication for people who were partially deaf or representatives for people whose first language was not English. Team members could also speak Romanian and Ghanaian languages to assist people if required. There were two seats available for people to wait for their prescriptions and some car parking spaces available outside the premises. The pharmacy's opening hours and the services that it offered were on display in the front window. There were also some leaflets available about other services.

The pharmacy team used baskets to hold medicines during the dispensing process. This helped to prevent any inadvertent transfer. Not all the staff were using dispensing audit trails. On selecting randomly dispensed medicines and opening the bags, there were no details marked on generated labels to indicate who had dispensed or assembled some of the medicines.

The team was a few days behind with the workload as there were still prescriptions waiting to be dispensed from 17 September 2019. There were also gaps on the shelves where the pharmacy did not have any stock of some common medicines such as inhalers and there were no current supply issues with these medicines. One corner of the pharmacy contained a tote with dispensed prescriptions that were owed. Some were for common medicines such as naproxen, others were for more expensive items. Generated labels were seen attached to the bag, staff stated that they only generated owing slips when people came in to collect their medicines. There was a risk that if the labels could become detached or lost, then the only record showing that the medicine was owed would also be lost. Many people who used the pharmacy's services during the inspection were being owed items and team members were not effectively signposting people to other providers when this happened.

Once prescriptions were dispensed, they were attached to bags and stored on shelves. Fridge items and CDs (Schedules 2-3) were identified or assembled at the time people came in to collect them. Schedule 4 CDs were not routinely identified although staff could identify some of the common CDs under this Schedule. Uncollected prescriptions were checked every two to three months.

Compliance aids were supplied to people who found managing their medicines difficult after the GP assessed this. The pharmacy ordered prescriptions on behalf of people, when they were received, details on prescriptions were cross-referenced against individual records or records on the system to help identify any changes or missing items. Queries were checked with the prescriber and audit trails were maintained to verify this. All medicines included in the compliance aids were now de-blistered and removed from their outer packaging. Descriptions of medicines within trays were provided but patient information leaflets (PILs) were not routinely supplied. There were also several unsealed compliance aids present in the back office and staff explained that compliance aids were routinely left unsealed overnight.

Medicines were provided to the care home as original packs. The home was responsible for ordering and checking prescriptions to ensure that all the items had been received. Details about allergies or sensitivities were obtained and marked onto the Medication Administration Record (MAR). Interim or mid-cycle items were dispensed at the pharmacy. PILs were routinely supplied. Staff had not been approached to provide advice regarding covert administration of medicines to care home residents. There were no residents described as receiving higher-risk medicines.

The pharmacy provided a delivery service on two or three days of the week and the team retained audit trails for this. CDs and fridge items were highlighted. The driver obtained people's signatures when they were in receipt of their medicines. Failed deliveries were brought back to the pharmacy, notes were left to inform people about the attempt made and medicines were not left unattended unless prior consent was obtained. Relevant risks such as if there were any pets or children present were checked by the team before the latter took place.

Staff were aware of risks associated with valproate. According to the team, the pharmacy previously used to have educational material to provide to people if required, this was discussed at the time. Staff had not seen any females in the at-risk group, identified as having been supplied the medicine. Prescriptions for higher-risk medicines were not routinely identified to enable pharmacist intervention, counselling or checking of relevant parameters to routinely take place. There was no information seen recorded about this. People prescribed warfarin were described as moving to Apixaban although some people receiving compliance aids were still being prescribed warfarin. This was supplied separately to the compliance aid but there were no checks made about the International Normalised Ratio (INR) here.

Medicines for the pharmacy were obtained from licensed wholesalers such as Alliance Healthcare, AAH and Sigma. Unlicensed medicines were obtained through Colorama or Sigma. Some invoices were seen to confirm this. The pharmacy was not yet complying with the European Falsified Medicines Directive (FMD). There was no guidance information present, software in place or relevant equipment seen.

Medicines were stored in an organised manner. Staff described checking medicines for expiry regularly but there was no schedule in place to verify when this had last taken place. Short-dated medicines were identified and there were no date-expired or mixed batches of medicines seen. CDs were stored under safe custody and medicines in the fridge were stored appropriately. The keys to the cabinet were maintained in a way that safeguarded against unauthorised access. Drug alerts were received by email, the process involved checking for affected stock and acting as necessary. An audit trail on the email system was seen to verify this. Occasionally, staff stored medicines in poorly labelled containers once they had been removed from their original containers. Ensuring the full and necessary details were recorded was discussed during the inspection.

Medicines returned by people for disposal were first stored on shelves in one back corner of the

pharmacy. This was separate from the pharmacy's main stock. There were designated containers available to store returned medicines once they had been processed. However, there were no containers available for hazardous or cytotoxic medicines. There was also no list to help the team to identify these medicines before they were disposed of. People returning sharps for disposal, were referred to the local council. Returned CDs were brought to the attention of the RP before being segregated in the CD cabinet.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate range of equipment and facilities it needs to provide its services safely. Its equipment is clean and well maintained.

Inspector's evidence

Current versions of reference sources and relevant equipment were seen. This included clean, crown stamped conical measures for liquid medicines, as well as counting triangles and a separate one for cytotoxic medicines. The team described using the NPA's information services if further assistance was required as well as online resources. Computer terminals were positioned in a way that prevented unauthorised access. The dispensary sink used to reconstitute medicines was clean. There was hot and cold running water available as well as hand wash. The fridge was operating appropriately.

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.