General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Telephone House Pharmacy, Next to Surgery, 71 High Street, SOUTHAMPTON, SO14 2NW

Pharmacy reference: 1095341

Type of pharmacy: Community

Date of inspection: 27/12/2019

Pharmacy context

This is a community pharmacy located next to a GP surgery in Southampton. The pharmacy dispenses NHS and private prescriptions. It sells a range of over-the-counter (OTC) medicines, delivers medicines, offers Medicines Use Reviews (MURs), the New Medicine Service (NMS) and seasonal flu as well as travel vaccinations. And it provides multi-compartment compliance aids to people if they find it difficult to manage their medicines.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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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 not all met	2.2	Standard not met	The pharmacy is not meeting the GPhC's minimum training requirements for the team as some members of the pharmacy team have been working at the pharmacy for longer than three months and are undertaking tasks without being enrolled on accredited training appropriate for this
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	There is evidence that pharmacy services are provided in a way that puts people's safety at risk. Medicines are being supplied unlawfully inside compliance aids with inappropriate instructions on generated labels, or appropriate warning labels and patient information leaflets. The type of compliance aid being used for some people also makes the process unsafe and unclear for people about how they should take their medicines. And, the pharmacy has no processes in place to ensure the safety of people prescribed higher-risk medicines
		4.3	Standard not met	The safety of medicines is compromised by inadequate management arrangements. Stock medicines are not appropriately packaged or labelled and several medicines have been de-blistered and removed from their outer packaging, the pharmacy has then stored them loose or placed them back inside the original packaging as loose tablets
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy generally operates in a satisfactory manner. Members of the pharmacy team generally deal with their mistakes responsibly, and they know to protect people's private information. But they don’t formally review their internal mistakes or always record enough detail for all the pharmacy’s 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 inspection took place just after the bank holiday period, hence the pharmacy was less busy with walk-in trade. However, parts of the dispensary were cluttered (see Principle 3) and there were risks observed with the pharmacy team’s practice as described under the various principles. The pharmacy held a range of documented standard operating procedures (SOPs) to support its services. They had last been reviewed in 2018, staff had signed them to indicate that they had been read and their roles were defined within them. Team members present knew their roles and responsibilities, they knew when to refer to the pharmacist and the activities that were permissible in the absence of the RP. However, an incorrect RP notice was on display and the inspection took place at midday. Displaying a correct RP notice is a legal requirement and this situation meant that people were provided with incorrect details about the pharmacist in charge at the time.

The workflow involved designated areas for the team to carry out some of the pharmacy’s activities. This included a separate area for staff to process and assemble prescriptions, a designated area for the responsible pharmacist (RP) to carry out the final accuracy-check and separate workspaces at the back for multi-compartment compliance aids. However, the latter was very cluttered with assembled compliance aids and stock stored on workspaces here haphazardly (see Principle 4).

Prescriptions were downloaded and printed in batches before being placed into colour co-ordinated baskets. This helped manage the workload. Staff stated that they recorded their own near misses. The RP explained that he passed prescriptions back to staff for them to rectify and learn from their mistakes and if team members made more than three mistakes in a day, the RP would spend some time with them to help highlight and encourage them to learn from this. Medicines that were similar were described as separated. However, on inspecting the near miss log there were several gaps and few entries. For 2019, there were entries seen recorded in March and April 2019 and only two entries in December 2019. The review of near misses was also described as an informal process, a discussion with the RP took place, but no details had been documented to verify the process. This limited the ability of the pharmacy to demonstrate that trends or patterns had been identified, rectified and acted upon.

The RP stated that the superintendent pharmacist (SI) handled incidents. The RP’s process involved apologising, checking relevant details, rectifying the situation and passing details to the SI. The only detailed reports seen had been raised by NHS England where the pharmacy team had been asked to report back to them about the situation. Root cause analyses of the incidents had subsequently been completed and they had been reported to the National Reporting and Learning System (NRLS). The RP stated that issues had been seen about obtaining specific brands for people and they tried to resolve this in-house. However, there was no information on display about the pharmacy’s complaints

procedure. This could mean that people may not have been able to raise their concerns easily.

The front section of the dispensary was open plan and to help protect people's details, staff described lowering their voices when people were in the pharmacy. Sensitive details on dispensed prescriptions awaiting collection could not be seen from the retail space, confidential waste was separated before being shredded. Summary Care Records had been accessed for emergency supplies and consent was obtained from people in writing to access this. An information governance policy was present to provide guidance to the team, but this was blank. There was also no information on display to inform people about how their privacy was maintained.

Staff present were not trained to identify signs of concern to safeguard the welfare of vulnerable people although they were trained as dementia friends. The RP was trained to level two via the Centre for Pharmacy Postgraduate Education (CPPE) and he stated that other members of the team were also trained through CPPE although this could not be verified. Staff present were advised to complete the appropriate training. There was policy information and contact details about the local safeguarding agencies present.

A sample of registers for controlled drugs (CDs) were seen and most of the RP record was maintained in line with statutory requirements. On randomly selecting some CDs that were held, their quantities corresponded to the balances stated in the registers. The minimum and maximum temperatures of the fridge were routinely monitored. This helped to ensure that temperature sensitive medicines were appropriately stored, and records were maintained every day to verify this. The pharmacy maintained a complete record for the receipt and destruction of CDs that were returned to them for disposal although pharmacist oversight was not always taking place for some of the most recent records. This was discussed with the RP at the time. The pharmacy also held appropriate professional indemnity insurance to cover the services provided. This was through the NPA and due for renewal after 31 May 2020. However, there were missing details about prescribers in the electronic private prescription register, some records of emergency supplies were documented with limited details about the nature of the emergency and there were incomplete details for records of unlicensed medicines.

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

Summary findings

The pharmacy has some members of its team carrying out tasks that they are not trained for or qualified in. This situation brings risks. It can affect how well the pharmacy cares for people and the advice that it gives. But the pharmacy does have adequate numbers of staff to ensure its workload can be managed appropriately. And, members of the pharmacy team understand their roles and responsibilities.

Inspector's evidence

Staff present during the inspection included the RP who was a regular locum pharmacist, a trained locum dispensing assistant who usually provided regular cover and a trained medicines counter assistant (MCA) who had been working as a dispensing assistant for the past six months. Other staff included the pharmacy manager who was an accuracy checking technician (ACT), four other dispensing assistants and a student who had been working as an MCA at the pharmacy for the past six months. The MCA working as a dispensing assistant and student had not been enrolled onto accredited training in line with their roles at the point of inspection. This was not in line with the GPhC's minimum training requirements as 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.

Some of the team's certificates for their qualifications obtained were seen. The MCA knew to ask appropriate questions before selling medicines over the counter and they referred to the RP when required. As they were a small team, details were discussed verbally amongst them, team meetings were held when required and their progress was described as being monitored informally. As part of their ongoing training, they took instructions from the RP, read trade publications and completed modules through on an online training platform. The RP described an expectation to complete the maximum number of Medicines Use reviews (MURs) but stated that there was no pressure to complete this.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises in general provide a suitable environment to deliver healthcare services. The pharmacy is largely clean and appropriately maintained. It has plenty of space to carry out its activities safely. But parts of it are cluttered, and some of its workspaces are untidy.

Inspector's evidence

The premises consisted of an average sized retail area and a much larger dispensary that extended into the back. This space also included an office, a small staff kitchenette area and facilities. The retail space was professional in appearance, fixtures and fittings here were modern and the pharmacy was clean, appropriately lit as well as suitably ventilated. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity. However, the carpet in the dispensary required vacuuming. There was enough space in the dispensary for the pharmacy's current volume of workload, but most of the back benches and space used to assemble compliance aids were quite cluttered and untidy with paperwork, compliance aids and stock. A signposted consultation room was available to provide services or private conversations, the entrance to this was kept closed but unlocked. The room was of a suitable size for its intended purpose. However, there was a sharps bin on the floor here and as the room was kept unlocked, unauthorised entry and risk of needle-stick injury was possible. The RP was advised to keep this room locked or remove the sharps bin.

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

Summary findings

The pharmacy doesn't always provide its services or store its medicines in a safe and effective way. Its procedure for assembling compliance aids is unsatisfactory and unsafe. The pharmacy stores some of its medicines inappropriately. And, although its team makes some checks to ensure that medicines are not supplied beyond their expiry date, the pharmacy's records about this are inadequate. But the pharmacy does obtain its medicines from reputable sources. And its team ensures that people with different needs can easily access the pharmacy's services

Inspector's evidence

The pharmacy's front entrance was accessed from the street and through a wide front door. There was also clear, open space inside the premises, and this helped people with wheelchairs to easily use the pharmacy's services. There were four seats available for people to wait for their prescriptions if needed. The pharmacy's opening hours and services provided were listed on the front door. Staff could speak Polish, Hindi and other South Asian languages if needed. The team described using gestures, written details and text messages to help communicate with people who were partially deaf. There was information on display to help the team to signpost people to other local organisations.

The pharmacy provided a delivery service and audit trails to verify this service were maintained. CDs and fridge items were identified. People's signatures were not usually obtained when they were in receipt of their medicines (unless CDs were being delivered) and the driver ticked the details on the audit trail. This was discussed at the time. Failed deliveries were brought back to the pharmacy, notes were left to inform people about the attempt made and medicines were not left unattended. Occasionally, medicines were left with an authorised neighbour after consent had been obtained for this.

The RP was not accredited to provide travel vaccinations. For the influenza vaccination service, there was relevant equipment present such as a sharps bin and adrenaline autopens in the event of a severe allergic reaction to the vaccine. At the point of inspection, the RP had vaccinated people but could not locate the private or NHS Patient Group Directions (PGD) that authorised him to vaccinate people. It could not therefore be verified that they had been signed and read by the RP. A copy of the declaration for the NHS PGD that had been signed in September 2019 was supplied by email following the inspection, but no details were seen or received about the private PGD.

The pharmacy provided a supervised consumption service for people. The local drug and alcohol action team called the pharmacy to inform them about new people, their details and dates of birth were then checked before the initial supply was made. There were no three-way agreements in place between the service providers, the people using the service and the pharmacy as the RP stated that details were discussed verbally with people. As the inspection started, dispensing staff were observed helping themselves to dispensed methadone that had been stored in one part of the pharmacy. Staff did not bring this to the attention of the pharmacist and proceeded to supply this without him being informed. After the inspector intervened and discussed appropriate pharmacist oversight, the RP took over and the dispensed methadone was subsequently placed into the CD cabinet.

The pharmacy supplied compliance aids after the person's GP initiated this. The pharmacy ordered

prescriptions on behalf of people, details on prescriptions were cross-referenced when they were received against either individual records or records on the pharmacy system to help identify any changes or missing items. Queries were checked with the prescriber and some audit trails were seen to verify this. Hospital discharge information was received and retained by the pharmacy. Compliance aids were not left unsealed overnight. All medicines were de-blistered into them with none supplied within their outer packaging. Mid-cycle changes involved the compliance aids being retrieved, amended, re-checked and re-supplied.

At the point of inspection, there were concerns with some of the packs that were being used to dispense medicines into and the pharmacy was not fully labelling details of the medicines supplied within them. Nor were descriptions of the medicines being provided or patient information leaflets (PILs) routinely supplied. Some of the packs being used were for care homes and normally used for residents as part of the racking system. Some of them had been cut to remove days of the week when the pharmacy supplied them. They were also being supplied to people in their own homes with insufficient details about the medicine. The labels generated only included the quantity of the medicine, the name, strength and form. There were no other warning details being included (for example with dispersible aspirin tablets) and the full dosage instructions were missing for each generated label. This was not in accordance with the law and meant that people were not receiving the full details about their medicines.

The team used baskets to hold prescriptions and medicines during the dispensing process and this helped prevent any inadvertent transfer. The baskets were colour co-ordinated to help identify different types of prescriptions such as those requiring delivery. A dispensing audit trail through a facility on generated labels was used and this identified staff involvement in processes. Dispensed prescriptions awaiting collection were stored in an alphabetical retrieval system. Dispensed fridge items and CDs (Schedules 2-3) were identified. The former were stored within clear bags once dispensed and this helped identify their contents upon hand-out. Schedule 4 CDs were not routinely marked to identify their 28-day prescription expiry. This was discussed at the time. Uncollected prescriptions were removed every three months.

Staff were aware of the risks associated with valproates. There was educational literature present to provide to people at risk and according to the RP, females in the at-risk group, had been identified and counselled appropriately before supplying the medicine. At the point of inspection, prescriptions for higher-risk medicines were not routinely identified to enable pharmacist intervention, counselling did not regularly take place and relevant parameters were not routinely checked or details documented. This was not in accordance with the pharmacy's SOPs.

Medicines were obtained from licensed wholesalers such as AAH, Alliance Healthcare, Sigma and Colorama. The latter was used to obtain unlicensed medicines. Most of the team was unaware of the European Falsified Medicines Directive (FMD). The pharmacy was not registered with SecurMed, its systems had been updated with the relevant software but there was no equipment in place and staff were not yet complying with the decommissioning process. Most of the pharmacy's medicines were stored in an organised manner on the dispensary shelves. Staff stated that they had previously date-checked medicines in the last month in the dispensary and tried to do this every month. Short-dated medicines were routinely identified. There were no date-expired medicines or mixed batches of medicines seen. CDs were largely stored under safe custody. Drug alerts were received via email, action was taken as necessary and an audit trail on the email system was seen to verify the process.

However, the date-checking schedule had gaps with the last details seen completed in April and October 2019. This limited the ability of the pharmacy to verify that regular checks had been taking

place. There were several poorly labelled containers present with missing details (such as batch numbers and expiry dates). This also included medicines that had been de-blistered and stored in bottles in the area where compliance aids were prepared. In addition, there were several de-blistered tablets and capsules that had been left in a saucer on one bench and several packs of medicines that contained loose tablets where they had been de-blistered and removed from their outer packaging and then placed as loose tablets back inside the original packaging.

Once accepted, the team stored returned medicines requiring disposal within designated containers. However, there was no list available for staff to identify them or designated containers to appropriately dispose of hazardous and cytotoxic medicines. 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

The pharmacy was equipped with current versions of reference sources and relevant equipment. This included a range of clean, standardised, conical measures, an appropriately operating fridge, a legally compliant CD cabinet and a clean sink that was used to reconstitute medicines. Hot and cold running water was available as well as hand wash. Computer terminals were positioned in a manner that prevented unauthorised access. Staff used their own NHS smart card to access electronic prescriptions and took them home overnight. A shredder was available to dispose of confidential waste and cordless phones enabled private conversations to take place away from the retail space if needed.

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.