General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: S.K. Roy Dispensing Chemists Ltd.;, 44 St Marys

Road, SOUTHAMPTON, Hampshire, SO14 0BG

Pharmacy reference: 1031899

Type of pharmacy: Community

Date of inspection: 09/10/2019

Pharmacy context

This is a community pharmacy located within a residential area of Southampton in Hampshire. The pharmacy dispenses NHS and private prescriptions. It sells over-the-counter (OTC) medicines, provides advice and delivers medicines. The pharmacy also supplies multi-compartment compliance aids to people in their own homes if they find it difficult to manage their medicines.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

Follow this link to find out what the inspections possible outcomes mean

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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 some risks associated with its services as failed under the relevant standards and Principles. Most of the pharmacy's standard operating procedures are missing, they have not been kept at the pharmacy and there is no evidence that the team has read them
		1.6	Standard not met	The pharmacy is not maintaining all of its records in accordance with the law. Records of supplies made against private prescriptions have not been kept since April 2019. 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, it therefore cannot demonstrate that it is making these supplies and records in line with the current legislation
		1.8	Standard not met	The pharmacy has no procedures in place to safeguard the welfare of vulnerable people and staff are unable to demonstrate any knowledge about this
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,				

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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Principle 1 - Governance Standards not all met

Summary findings

The pharmacy doesn't 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 deal with their mistakes responsibly. They understand how to protect people's private information. But, they are not always 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. And, team members don't understand how to protect the welfare of vulnerable people. There are no procedures in place to guide them on this. So, they may not know how to respond to concerns appropriately. 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 retail space was in general, professional in appearance although the dispensary was cluttered (see Principle 3) and the team was slightly behind with the workload. During the inspection, the responsible pharmacist (RP) and superintendent (SI) was managing the front walk-in trade whilst staff worked in the dispensary behind. The workflow involved designated areas for the team to carry out some of the pharmacy's activities. This included a separate area for processing repeat requests of prescriptions, a workspace at the back for multi-compartment compliance aids to be assembled and set areas for staff to dispense repeat and walk-in prescriptions.

To manage risks, staff explained that during the dispensing process they lined up the medicine(s) so that a three-way check of the product, label and prescription could take place. Staff were routinely recording their near misses and explained that they separated similar medicines, placed other stock in between to help differentiate them and placed caution stickers in front of stock as an additional visual alert. However, the review of near misses was informal, a discussion with the RP took place and no details were documented to verify the process.

There was information on display about the pharmacy's complaints procedure. The RP handled incidents and his process involved apologising, checking relevant details, rectifying the situation, informing the person's GP if anything was taken incorrectly, recording details and reporting the incident to the National Pharmacy Association (NPA) so that this could be passed to the National Reporting and Learning System (NRLS). Previous records of incidents were seen, and the last incident involved an incorrect product being supplied that was similar to the correct medicine. They were separated, and staff awareness raised.

Staff described reading information about the EU General Data Protection Regulation (GDPR), they muted phone calls to help protect people's private details and lowered their voice when people were in the pharmacy. Sensitive details on dispensed prescriptions awaiting collection could not be seen from

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the retail space, confidential waste was separated before being disposed of through an authorised carrier and there was information on display to inform people about how their privacy was maintained.

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. The correct RP notice was on display and this provided details of the pharmacist in charge on the day. However, the RP had taken the documented standard operating procedures (SOPs) home with him and only one or two SOPs were present on site that were about the management of higher-risk medicines. Staff stated that they had read the SOPs although the apprentice said that she had only read some of them. This could not be verified.

Staff were not trained to identify signs of concern to safeguard vulnerable people, this included the trained members of the team as well as the RP who had not completed any formal training at the point of inspection. There was no local policy information, or an SOP seen to provide the team with guidance. Local contact details about the safeguarding agencies were present.

A sample of registers for controlled drugs (CDs), most of the RP record and emergency supplies in general were maintained in line with statutory requirements. On randomly selecting some CDs that were held, their quantities corresponded to the balances stated in registers. The minimum and maximum temperatures of the fridges 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. The pharmacy also held appropriate professional indemnity insurance to cover the services provided.

However, the team had not been routinely maintaining records of supplies made against private prescriptions as the last documented records were from April 2019 and a bundle of private prescriptions that had been dispensed since then were seen. This was discussed at the time. In addition, the RP had taken the records of unlicensed medicines home with him. It was therefore not possible to verify whether they had been kept in accordance with the law.

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Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy has enough staff to manage its workload safely. Members of the pharmacy team understand their roles and responsibilities and have access to resources to keep their knowledge current. But, some members of the team are 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.

Inspector's evidence

Staff present during the inspection included the RP, a trained locum dispensing assistant, a full-time pharmacy apprentice and a part-time member of staff who was responsible for admin such as ordering and processing repeat prescriptions, dealing with queries and collecting prescriptions from local surgeries. This member of staff did not process, dispense prescriptions or put stock away. There was also another part-time assistant described as having the same administrative role as well as a medicines counter assistant (MCA) who had recently started working at the pharmacy, two further dispensing assistants and MCA. The latter three were not enrolled onto accredited training for their roles and had worked at the pharmacy for longer than three months. This is 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.

Staff wore name badges but certificates for staff qualifications obtained were not seen. The RP was serving people, selling medicines and providing advice during the inspection. The apprentice and dispensing assistant knew to ask appropriate questions before they sold OTC medicines and they referred to the RP when required. The RP was also observed coaching staff including the apprentice about the pharmacy's internal processes. As they were a small team, details were discussed verbally amongst them, their progress was described as being monitored informally and although they mostly took instructions from the RP, the pharmacy team could further their knowledge as training packs and modules were available through Avicenna.

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Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy's premises in general provide an appropriate environment for the delivery of healthcare services. The pharmacy is clean and secure although parts of it are cluttered and untidy.

Inspector's evidence

The premises consisted of a medium sized retail area and dispensary. There was also a small staff kitchenette area and facilities at the very rear as well as two signposted consultation rooms in the retail space. The latter was generally professional in appearance, fixtures and fittings were modern and the pharmacy was clean, bright as well as suitably ventilated. Pharmacy (P) medicines were stored behind the front counter and staff were always within the vicinity. The front counter also consisted of a separate area to one side to help assist with counselling people or for private conversations to take place.

Only one of the consultation rooms was used to provide services or private conversations, the entrance to this was kept locked. Both rooms were of a suitable size for their intended purpose. The second consultation room contained confidential information as staff processed prescriptions in here. This was not seen to be used during the inspection and was located behind the front counter.

However, there were several boxes present in the retail space that had not been put away. This detracted somewhat from the overall appearance. There was enough space in the dispensary for the pharmacy's current volume of workload, but most of it was cluttered. In addition, there were also several totes of medicines that had been delivered from the past week that not been put away. This was taking up significant room in the dispensary and limited free movement of the team.

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Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy team is helpful and tries to ensure that people with different needs can easily access the pharmacy's services. The pharmacy generally provides its services in a safe manner. It takes extra care with people prescribed higher-risk medicines so that they can take their medicines safely. And, the pharmacy sources, largely stores and manages its medicines appropriately.

Inspector's evidence

The pharmacy's opening hours and a noticeboard to provide information to the local community was on display. There were also a few seats available for people waiting for their prescriptions. People could enter the pharmacy from the street and the clear, open space inside the retail area helped people using wheelchairs to easily access the pharmacy's services. Staff verbally communicated information to people who were visually impaired, they used written communication for people who were partially deaf and spoke Urdu, Hindi, Punjabi, Bengali as well as Italian to help communicate with people if their first language was not English.

Compliance aids were supplied and initiated after the RP carried out an assessment for suitability. The pharmacy ordered prescriptions on behalf of people and staff cross-referenced details on prescriptions against the repeat requests. This helped them to identify any changes and records were maintained to verify this. All medicines were de-blistered into the compliance aids with none supplied within their outer packaging. They were not left unsealed overnight when assembled. Descriptions of medicines were provided and patient information leaflets (PILs) were routinely supplied. People prescribed warfarin and methotrexate who received compliance aids were supplied these separately. Mid-cycle changes involved the compliance aids being retrieved, amended, re-checked and re-supplied.

Medicines were delivered by staff or by the RP's wife and the pharmacy maintained records to verify the process. Staff called people before attempting to deliver, they obtained signatures from people when they were in receipt of their medicines and failed deliveries were brought back to the pharmacy. The team texted or called people to inform them of the attempt made to deliver.

The pharmacy operated a repeat prescription ordering system where they ordered prescriptions for people on their behalf. One member of staff was responsible for this process and the section of the dispensary where they worked and maintained records was observed to be kept in an organised manner. The process involved calling people and checking which medicines were required, sending the repeat request to the person's GP surgery, monitoring any changes or missing items and keeping audit trails to verify this. Staff explained that they also re-checked with people which medicines had been required upon hand-out.

The team used a dispensing audit trail through a facility on generated labels. This identified their involvement in processes. Staff used baskets to hold prescriptions and associated medicines and this

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helped prevent any inadvertent transfer. Staff were aware of risks associated with valproates and educational material was available to provide to people if required. Prescriptions for people prescribed higher-risk medicines were identified so that counselling could take place and relevant parameters checked. This included asking and obtaining details about the International Normalised Ratio (INR) level for people prescribed warfarin. The pharmacy kept records to verify that this had been taking place. Dispensed prescriptions with fridge items or CDs (Schedules 2-4) were routinely identified.

The pharmacy obtained its medicines and medical devices from licensed wholesalers such as Alliance Healthcare, AAH, Phoenix and OTC Direct. Unlicensed medicines were obtained through Avicenna. Staff were unaware of the process involved for the European Falsified Medicines Directive (FMD). The RP confirmed that the pharmacy was not yet registered with SecurMed or complying with the decommissioning process. There was no guidance information present or seen for the team.

Apart from the boxes of totes described in Principle 3, medicines were generally stored in an organised manner in the dispensary. Staff explained that they date-checked medicines for expiry upon receipt from wholesalers and during the dispensing process, there were also some recent records to verify that this had been taking place. Short-dated medicines were identified using coloured stickers. There were no date-expired medicines or mixed batches of medicines seen. CDs were stored under safe custody and keys to the cabinet were maintained in a manner that prevented unauthorised access during the day and overnight. Medicines were stored at appropriate temperatures in the fridge and dispensed CDs and fridge items were placed inside clear bags. This helped assist in identifying and verifying the contents upon hand-out.

Staff stored medicines returned for disposal within designated containers prior to collection and there was a list available to assist the team to identify cytotoxic and hazardous medicines. People returning sharps for disposal were referred to the local council and any returned CDs were brought to the attention of the RP prior to appropriate storage and destruction. The team received drug alerts by email, the process involved checking for affected stock and acting as necessary. An audit trail was seen on the pharmacy's email system to verify the process.

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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 counting triangles, a separate one for cytotoxic medicines, clean, standardised, conical measures, an appropriately operating fridge, a legally compliant CD cabinet and there was 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. The pharmacist used his own NHS smart card to access electronic prescriptions and took this home with him overnight. Cordless phones were also available for private conversations to take place away from the retail space if needed.

What do the summary findings for each principle mean?

✓ Excellent practice
 ✓ Excellent practice
 ✓ Excellent practice
 ✓ Excellent practice
 ✓ The pharmacy services which benefit the health needs of the local community, as well as performing well against the standards.
 ✓ 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
 ✓ Standards met

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Standards not all met

The pharmacy has not met one or more standards.

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