General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Coombe Hill Pharmacy, 3 The Triangle, KINGSTON UPON THAMES, Surrey, KT1 3RU

Pharmacy reference: 1036648

Type of pharmacy: Community

Date of inspection: 29/10/2020

Pharmacy context

This is a community pharmacy on a parade of shops in Kingston Upon Thames in Surrey. The pharmacy dispenses NHS and private prescriptions. It offers Medicines Use Reviews (MURs), the New Medicine Service (NMS), flu vaccinations and a local delivery service. The pharmacy also supplies people with their medicines inside multi-compartment compliance packs if they find it difficult to take their medicines. This was a targeted inspection as intelligence had been received that the pharmacy had been obtaining unusually large quantities of codeine linctus which is addictive and can be abused. The inspection was conducted during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 has not adequately identified or managed the risks associated with selling codeine linctus over the counter. It has been purchasing and selling large amounts of codeine linctus. The pharmacy does not have the appropriate governance in place to manage this situation and there are no documented details about the action it has taken to ensure medicines which are addictive, can be abused and misused are sold safely. This means people's health is at risk.
		1.2	Standard not met	The pharmacy is not selling codeine linctus safely. It does not have any systems in place or audit trails to identify, monitor and review sales of this medicine.
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 not all met	4.2	Standard not met	The pharmacy is purchasing and selling excessive amounts of codeine linctus without the appropriate safeguards in place to prevent its misuse and abuse.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy does not have the appropriate safeguards in place to identify, monitor and manage all the risks associated with selling codeine linctus. It is buying and selling large amounts of some medicines that could be abused and cause harm. This risks people's safety. The pharmacy's practices relating to its other services are generally safe. This includes managing the risks associated with COVID-19. And the pharmacy protects people's private information appropriately.

Inspector's evidence

The pharmacy was clean, tidy and organised. It had a range of standard operating procedures (SOPs) to provide guidance to the team about the services it provided. They had been reviewed in February 2020 and were from the National Pharmacy Association (NPA). The SOPs had been annotated to reflect the pharmacy's internal procedures. Most of the staff had read and signed them except for the pre-registration pharmacist who stated that she had read them. There was an SOP for selling over-the-counter (OTC) medicines. However, this only briefly mentioned referring to the responsible pharmacist (RP) before selling medicines that could be misused such as those containing codeine or promethazine (Phenergan). There was no further documented, policy or specific information on how to manage excessive requests or the risks of selling these medicines.

The pharmacy's team members, including the RP were aware that OTC codeine containing medicines were addictive. The RP, who was also the owner explained that the pharmacy had not dispensed any NHS or private prescriptions for codeine linctus. He confirmed the team had been selling codeine linctus over the counter due to an increase in requests to purchase this. The RP described groups of young boys initially requesting this medicine and he believed this was because it was being misused to make 'purple drank'. The RP said that after the team noticed this happening, the requests had been refused and sales blocked. But he stated that the same group had then targeted people in the area. The RP described the boys standing around outside the pharmacy asking people to purchase the codeine linctus for them. The RP said that he had contacted and informed the police several times about this. The police had set up a community watch group and had initially been more visible, increasing their patrols in the local area to help combat this. The pharmacy had also been assigned a named police constable (PC) for them to contact whenever they had concerns or saw people standing around outside the pharmacy. The RP described being in regular contact with this PC and often called her to report suspicious activity. This was described as being three to four times a week.

The RP said that since then, requests for codeine linctus now had to go through him. He asked about symptoms, tried recommending other products and used an established sales-of-medicines protocol (WWHAM) before selling codeine linctus. He said that people were requesting this for a dry cough and different people came in. If the RP noticed the same person making the request, the sale was refused. The RP stated that he found it difficult to refuse sales if repeat requests or purchases by the same people were not seen. Staff also described experiencing verbal abuse and ongoing issues if sales were refused or challenged. The RP explained that bottles of codeine linctus were being sold at £9.99 and said that this price was intended to deter sales.

However, other than one online review from someone who had been refused codeine linctus by the RP's wife, the team had not documented any details of the refusals. This limited the ability of the

pharmacy to demonstrate that its team members had been taking appropriate steps to prevent misuse from happening. There had been no details documented of any interventions made with OTC sales or codeine linctus and there were no written records of the sales. The RP could not say exactly how many requests for codeine linctus were seen in a day, week or month. The pharmacy used an old-fashioned cash register where prices of medicines were manually entered before selling the product to people. This meant that the pharmacy could not identify, monitor or break down the sales of codeine linctus compared to the sales of other medicines over any period. Consequently, this meant that there was no or very limited oversight of the requests and sales of this medicine. There were also no risk assessments or documented details completed about this situation or records of the conversations with the police. At the end of the inspection, the RP asked the inspector if he could stop selling codeine linctus and said that he would do so now.

The pharmacy had systems in place to identify and manage the risks associated with some of its other services. This included limiting the spread of infection from COVID-19. The premises had been modified (see Principle 3). Information was displayed at the entrance asking people to wear a mask upon entering and that only two people at a time could enter the premises. The team had been provided with personal protective equipment (PPE) and staff were wearing masks at the time of the inspection. They washed their hands frequently and used hand sanitisers. People using the pharmacy's services had a designated pen to sign prescriptions. The pharmacy was cleaned regularly. Risk assessments for COVID-19, including occupational ones for the team had been completed. The RP had thought about the pharmacy's business continuity plan. Documenting details, including SOPs about coronavirus and the requirement to report any cases of staff contracting COVID-19 during work was discussed with him at the time.

Staff routinely recorded their near miss mistakes. They were formally reviewed every month and discussions were held with the team. Medicines that had been involved in errors, were identified. Dividers had been placed between medicines to help identify and prevent mistakes from happening again. A list of common look-alike and sound-alike medicines was on display along with details of the 'HELP' mnemonic.

The pharmacy protected people's confidential information appropriately. There were no sensitive details that could be seen from the retail space. Confidential waste which was shredded. Computer systems were password protected and staff used their own NHS smart cards to access electronic prescriptions. The RP had been trained to level two to safeguard the welfare of vulnerable people through the Centre for Pharmacy Postgraduate Education (CPPE). The trained dispensing assistants could recognise signs of concern. Staff knew who to refer to in the event of a concern. Contact details for the local safeguarding agencies were present. However, the newest member of staff who worked as a counter assistant had not yet been trained on safeguarding vulnerable people (see Principle 2).

The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display. The pharmacy's records were largely compliant with statutory and best practice requirements. This included a sample of registers seen for controlled drugs (CDs), electronic records of emergency supplies, records of unlicensed medicines and the private prescription register. On randomly selecting CDs held in the cabinet, their quantities matched the stock balances recorded in the corresponding registers. The pharmacy's professional indemnity insurance was through the NPA and due for renewal after 31 August 2021. Records of CDs that had been returned by people and destroyed at the pharmacy had been maintained and records verifying that fridge temperatures had remained within the required range had been completed. However, there were gaps within the electronic RP record where pharmacists had not always recorded the time that their responsibility ceased. This was discussed at the time. On checking the private prescription register, routine prescribing of Schedule 4

CDs (diazepam) on private prescriptions had been dispensed at the pharmacy on a weekly basis for the past few weeks. The quantities prescribed were not greater than 28 days but there had been no checks made as to the appropriateness of these.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload appropriately. Team members have completed the required training for their roles or are enrolled onto suitable training courses. And the pharmacy provides them with enough material for their ongoing training. This helps keep the team's knowledge and skills up to date. But not all the team have been trained on medicines that could be abused or on how to safeguard vulnerable people. This increases the risk of harm for people using the pharmacy's services.

Inspector's evidence

The pharmacy's staffing profile included the regular RP, who was the owner and had worked at the pharmacy for the past seven years, another pharmacist who was his wife, a pre-registration trainee whose employment had started in August 2020, two trained dispensing assistants, one of whom was undertaking training for the NVQ 3 in dispensing and a medicines counter assistant (MCA). The latter had started working at the pharmacy since the pandemic started and was undertaking accredited training with the NPA. Certificates of the staff's training were on display verifying their qualifications. The RP described the pharmacy being under pressure at the start of the year because of COVID-19 and the team had worked longer hours to stay on top of the workload. This situation had since settled. The team was up to date with the workload and the pharmacy had enough staff to manage its volume of dispensing.

The pre-registration trainee had quiet periods to study, the RP was her tutor and she had a training plan in place. The MCA explained that she had also been completing her course material at work. She held some knowledge about OTC products. The MCA asked relevant questions before selling OTC medicines, asked about other medical conditions, symptoms, intended use and knew when to refer to the RP if she was unsure or if excessive requests were seen. When questioned, the MCA explained that two packs of codeine containing medicines could not be sold any one time, but the inspector was told that she would sell two packs of pseudoephedrine containing medicines.

The MCA's activities could be supervised easily from the layout of the pharmacy. The RP was always in the vicinity, the dispensary was raised above the counter and staff working in the dispensary could easily monitor her activities. However, the MCA had not yet been trained on safeguarding vulnerable people but had seen some details in her course material. The lack of training for a front-line member of staff increases the risks associated with the pharmacy's purchases of large amounts of medicines that could be abused. The MCA could also not fully explain what her professional obligations involved to ensure people's safety when they used the pharmacy's services. Other trained members of the team could do this.

Team members were observed to work well together and required little direction from the RP. Staff were also provided with opportunities and resources for ongoing training. The team's performance was informally monitored, and informal, ad-hoc meetings and discussions were held when required. The RP was observed informing the staff about points raised by the inspector during the inspection to ensure their working practices were safer.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy's premises provide a suitable environment to deliver healthcare services. The pharmacy has introduced suitable measures to help reduce the spread of COVID-19 inside its premises. And it has a separate space where confidential conversations or services can take place.

Inspector's evidence

The pharmacy's premises were professional in appearance. The pharmacy was clean, bright and well ventilated. The pharmacy's retail space was somewhat smaller than the dispensary, but the latter had plenty of space to carry out dispensing tasks safely. There were several workstations for different activities to take place. A signposted consultation room was present for private conversations and services. The premises had also been adapted to help ensure social distancing and reduce the spread of infection. A notice was on the entrance about how many people could enter at any one time and markers on the floor indicated where people should stand. A screen had been positioned in front of the medicines counter as a barrier and hand sanitisers were available for people to use.

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

Summary findings

The pharmacy does not provide all its services safely. It has limited systems to ensure supplies or sales of higher-risk medicines are made safely. It is unable to satisfactorily justify the large quantities of codeine linctus and other medicines liable to abuse that it orders and supplies. And it is not doing enough to satisfy itself that people are not at risk of becoming addicted. The pharmacy provides most of its other services in an appropriate way. It obtains its medicines from reputable sources. And it stores as well as manages its medicines appropriately.

Inspector's evidence

People could enter the premises from the street. This meant people with wheelchairs or restricted mobility could easily enter the pharmacy. Car parking spaces were available outside the premises. The pharmacy's services were advertised. Supervised consumption of methadone had ceased since coronavirus and people had been provided their medicines to take away instead. The RP explained that fewer Medicines Use Reviews (MURs) had been conducted since COVID-19 but the flu vaccination service was being provided. This was being managed through appointments to help reduce the amount of time spent in the pharmacy and the number of people present at any one time. The RP had been appropriately trained on vaccination techniques and resuscitation in the event of an emergency. Suitable equipment was present such as adrenaline in the event of a severe reaction to the vaccine. This helped to ensure that the service was provided safely. The service specification and patient group directions (PGDs) to authorise this were readily accessible and had been signed by the RP. PPE was worn during consultations. The pharmacy also provided a smoking cessation service run by the RP. He described the pharmacy winning awards in 2018 and 2019 for the best performing pharmacy for this service. The RP factored this down to his enthusiasm for the service, he said that he enjoyed helping people to quit and had built up a rapport with people who used the pharmacy's services.

Some people's medicines were supplied inside multi-compartment compliance packs once the RP or person's GP had identified a need and liaised about this. The pharmacy ordered prescriptions on behalf of people for this service and specific records were kept for this purpose. Any queries were checked with the prescriber and the records were updated accordingly. Descriptions of the medicines inside the packs were provided. Routinely supplying patient information leaflets (PILs) was discussed during the inspection. The pharmacy's driver delivered people's medicines to them and the team kept records about this service. Contactless deliveries were being made due to COVID-19. Failed deliveries were brought back to the pharmacy, notes were left to inform people about the attempt made and medicines were not left unattended.

The workflow involved prescriptions being prepared in one area, the RP checked medicines for accuracy from another section and a designated space was used to assemble compliance packs. The team used baskets to hold prescriptions and medicines during the dispensing process. This helped prevent any inadvertent transfer. Once staff generated the dispensing labels, there was a facility on them which helped identify who had been involved in the dispensing process. Team members routinely used these as an audit trail.

Staff were aware of the risks associated with valproates, a poster was on display about this and there was literature available to provide to people at risk. However, the pharmacy team had not routinely

been asking relevant questions for people prescribed other higher-risk medicines such as warfarin. Prescriptions for higher-risk medicines were not identified, questions were not asked about blood test results and details were not documented. The RP and pre-registration trainee gave a recent example of how the pharmacy had noticed an incorrect dose for a prescription for Helicobacter pylori infection and how they had rectified this. However, there were no documented details of this, other interventions or interventions made for OTC sales. The RP said that he did not know that the pharmacy should be making and recording details of interventions for the latter.

The pharmacy used licensed wholesalers such as AAH, Alliance Healthcare, Doncaster, Colorama and OTC to obtain medicines and medical devices. The team date-checked medicines for expiry regularly and kept records of when this had happened. Short-dated medicines were identified. There were no date-expired medicines or mixed batches seen.

Dispensing staff explained that they manually ordered stock for the counter when they visually noticed that supplies had run out or were low. This included codeine linctus. Invoices detailing the purchase of codeine linctus that were present on the premises were obtained. Following the inspection, the RP sent invoices detailing the purchases of Phenergan Elixir.

The RP confirmed that there had been no breakages, theft or break-ins at the pharmacy relating to codeine linctus. The pharmacy did not have an online presence. The RP also confirmed the pharmacy was not supplying any other organisation or pharmacy with this medicine. The pharmacy did not have a wholesale distribution authorisation (WDA).

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment and facilities it needs to provide its services safely. Its equipment is clean. And used appropriately to protect people's private information.

Inspector's evidence

The pharmacy held current versions of reference sources, counting triangles, a tablet-counting and de-blistering machine, legally compliant CD cabinets and an appropriately operating pharmacy fridge. The dispensary sink for reconstituting medicines was clean. There was hot and cold running water available. However, alongside a range of standardised conical measures, plastic ones were present. The importance of using standardised measures for accurate results was discussed at the time, the RP agreed to stop using these and purchase new ones. The consultation room was cleaned before and after being used for services due to COVID-19. Computer terminals were positioned in a manner that prevented unauthorised access. The pharmacy had cordless telephones so that private conversations could take place if required and a shredder to dispose of confidential waste.

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.