General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Gatley Pharmacy, 220 Liverpool Road, Eccles,

MANCHESTER, Lancashire, M30 OPF

Pharmacy reference: 1091644

Type of pharmacy: Community

Date of inspection: 28/07/2020

Pharmacy context

This community pharmacy is located in a row of shops on a main road. Most people who use the pharmacy are from the local area. The pharmacy mainly dispenses NHS prescriptions and it has a home delivery service. It supplies a large number of medicines in multi-compartment compliance aid packs to help people take their medicines at the right time. The pharmacy sells a range of over-the-counter medicines. This was a targeted inspection as information had been received that the pharmacy had been obtaining an unusually large quantity of codeine linctus, which is addictive and liable to abuse and misuse.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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 does not have adequate systems to identify and manage risks when selling medicines which are liable to abuse, overuse or misuse, in particular codeine linctus.
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 sells large amounts of codeine linctus without making appropriate checks to safeguard against misuse.
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 identify and manage all of the risks involved with its services, especially in relation to sales of codeine linctus. This means that there are some risks to patient safety and vulnerable people might be able to obtain medicines that could cause them harm. Pharmacy team members understand how to keep people's private information safe and they generally work to professional standards. But some team members have not confirmed their understanding of the pharmacy's written procedures, so they may not always work effectively or fully understand their roles and responsibilities.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) for the services provided which had been last reviewed in June 2018. There were signatures showing that some members of the pharmacy team had read and accepted the SOPs. However, the pharmacist superintendent (SI), the dispenser and the trainee medicine counter assistant (MCA), had not indicated that they had read the SOPs. Members of the pharmacy team were carrying out duties consistent with their role. But the 'Roles and responsibilities of pharmacy staff' SOP, with a staff competency and task matrix had not been completed. And there was no procedure stating which members of the pharmacy team were competent to perform certain tasks, such as giving advice about medicinal products, so this might not be clear to all.

The SI said there was a high demand for codeine linctus over-the-counter (OTC). He said he had discussed the high number of requests with the other regular pharmacist when he started working at the pharmacy around 16 months ago, but they had decided to continue to sell it. The SI said he received around five to ten requests for codeine linctus each day. He made a judgement call each time when selling codeine linctus and didn't allow more than one bottle to be sold to the same person more than once each week. He said a diverse range of people requested codeine linctus. He refused some sales but authorised six or seven sales each day. There was nothing in place to monitor the number of requests for these types of medicines and no written records of sales or refusal of sales for codeine linctus. This was a risk as there was no way of sharing information or concerns with the other regular pharmacist. The SI said information about codeine sales was not recorded on the patient's medication record (PMR) as people purchasing codeine linctus did not usually obtain their prescriptions from the pharmacy, so they did not have a PMR. The SI said he could recall one occasion when he suggested to a person, when he was refused a sale of codeine linctus, that he could get help from the drug and alcohol misuse service. But he had never really considered that selling codeine to people who might be addicted, was a possible safeguarding concern. This intervention had not been recorded, and the SI said he had not seen this person again, so did not know if he had received any help. The SI told the inspector at the end of the inspection, that due to the risks highlighted during the inspection, and the serious way the GPhC were taking the intelligence, he had decided to stop selling codeine linctus in the pharmacy.

The SI said he had only seen one or two prescriptions for codeine linctus since he started work in the pharmacy. There were no two litre stock bottles of codeine linctus in the dispensary, but the SI said a few two litre bottles had been obtained when the 200ml size were unavailable. These were split and used for OTC sales. This was not in line with Human Medicines Regulations as it altered the marketing authorisation of the codeine linctus, which is a schedule 5 controlled drug, and means its classification

changed from a pharmacy (P) medicine to that of a prescription only medicine (POM).

Most members of the pharmacy team did not wear uniforms or anything to indicate their role, so this might not be clear to members of the public. And the dispenser was casually dressed in jeans and a tee shirt, which did not present a professional image. The name of the responsible pharmacist (RP) was displayed as per the RP regulations.

The SI confirmed he had had carried out a COVID-19 risk assessment where he had considered the risks of coronavirus to the pharmacy team and people using the pharmacy. He had completed a template from the PSNC website to review social distancing and infection control. There were information notices in the pharmacy's window about COVID-19, and reminders of the requirement to maintain social distancing. Stretch barriers were used to ensure adequate space in front of the medicine counter and Perspex screens had been installed to reduce the risk of cross contamination between customers and staff. The touch surfaces, such as the front door handles, were cleaned every half hour, and this was documented on a cleaning rota. Staff risk assessments had been completed for most of the pharmacy team members. Some members of the team had been rated as at moderate risk but none of the team were wearing any personal protective equipment (PPE) during the inspection. The SI explained that he had made PPE available for team members but he did not insist that they wore it. He said he found that wearing a face mask was uncomfortable as it made him very hot, so he chose not to wear one. The trainee dispenser said she did not like to wear a face mask or a visor, although she confirmed that both of these had been made available for her to use.

There was a 'Dealing with Dispensing Errors' SOP and the SI confirmed that dispensing errors were always reported. Near misses were recorded on logs, which were on display in the dispensary. There were individual logs for the pre-registration pharmacists. The SI explained that this was so he could review this on an individual basis for these two members of the team. The SI said one member of the pharmacy team carried out patient safety reviews, but these were not available at the pharmacy. So, there was a risk that other team members could miss out on opportunities to learn from incidents.

Insurance arrangements were in place. The certificate of professional indemnity insurance on display had expired, but this was replaced with a current certificate when this was pointed out to the SI. There was a SOP describing the pharmacy's complaints procedure.

The pharmacy had policies for protecting people's data. Confidential waste was collected in a designated place and the pharmacy had a shredder. There were a large number of bags of confidential waste which had not been shredded. These were stored in the basement and the SI said he was going to arrange for this to be collected by an appropriate waste disposal company. The trainee dispenser had signed a confidentiality agreement as part of her training course.

There was guidance available on safeguarding vulnerable adults and children, which contained the contact numbers of who to report concerns to in the local area, and the pharmacy had a 'Chaperone' SOP. The SI, the other regular pharmacist and the pharmacy technician (PT) had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding. The trainee dispenser had completed level 1 training, but other members of the team, including the qualified dispenser had not completed any formal training on safeguarding, so they might be less confident recognising vulnerable people and the signs of neglect or abuse, or how to voice their concerns.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage its workload. The pharmacy team members work well together. They have access to appropriate training and some team members have worked at the pharmacy for several years so they are knowledgeable and experienced.

Inspector's evidence

The SI was working as the RP. There were two pre-registration pharmacists, a pharmacy technician (PT), an NVQ2 qualified dispenser (or equivalent), a trainee dispenser, a trainee medicines counter assistant (MCA) and a delivery driver on duty at the time of the inspection. The pharmacy's workload had increased as a result of the COVID-19 pandemic. The pharmacy was open Monday to Friday 9am to 6pm and Saturday 9am to 12pm. The team had maintained their usual opening hours throughout, but the SI and some staff had needed to work overtime to ensure all work was completed. The staffing level was adequate for the volume of work during the inspection. And the team were observed working collaboratively with each other and the patients. Some of the pharmacy team members were experienced. The qualified dispenser had worked in the pharmacy for around 12 years and the trainee dispenser for around 14 years. The SI worked at the pharmacy four to five days each week and the other regular pharmacist, who was the previous SI, worked two to three days each week. The SI was an experienced pharmacist and had started working at the pharmacy in March 2019. He had been appropriately trained for the travel vaccination service he carried out and there was a certificate showing this.

The trainee MCA had worked at the pharmacy for around eight months. Her role included advising people about pharmacy medicines, which she was not qualified to do. She had not been enrolled onto an accredited MCA training course, which was a requirement of the GPhC's minimum training requirement, which meant there might be key gaps in her skills and knowledge. The SI said he did not realise this was a requirement and said he would enrol the assistant as soon as possible; he provided confirmation of this shortly after the inspection. The assistant demonstrated that she had competed some Counter Skills training, and this included modules on cough and cold, pain relief, Mentholatum and Tena products. The trainee dispenser had completed the first module of 5 in the dispensing assistant course, which she had started in November 2019. She said it had not been possible to complete much training since the onset of the pandemic, due to the increased workload.

The SI said the pharmacy team were given formal appraisals where performance and personal development were discussed. He said these were documented but he was unable to locate the records during the inspection. The trainee dispenser confirmed that she had taken part in annual appraisals. The SI held weekly team huddles where concerns could be raised and discussed. These meetings were not documented, so there was a risk that issues raised might not be followed up or properly addressed.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy premises are safe, secure, and suitable for the pharmacy services provided.

Inspector's evidence

The pharmacy premises, including the shop front and facia, were clean, well maintained and in a good state of repair. The retail area was free from obstructions and professional in appearance. The temperature and lighting were adequately controlled. The pharmacy was fitted out to a good standard, and the fixtures and fittings were in good order. There was a basement where excess dispensary and retail stock was stored. Staff facilities were on the first floor and consisted of a kitchen area and WC with a wash hand basin and antibacterial hand wash. There was hot and cold running water. There was a separate dispensary sink for medicines preparation. Hand sanitizer gel was available at various locations for the pharmacy team to use, and there was also a foot operated pump for people to use in the retail area.

The consultation room was uncluttered, clean and professional in appearance. The SI explained that the pharmacy team were not routinely using the room during the pandemic, but it had previously been used when carrying out services such as travel vaccinations, and when customers needed a private area to talk. It was locked throughout the inspection.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy offers a range of healthcare services, most of which are generally well managed and easy for people to access. It gets its medicines from licensed suppliers and the team carries out some checks to ensure medicines are in suitable condition to supply. But the pharmacy does not make enough checks to make sure pharmacy medicines which are liable to abuse are appropriate for the people they supply. This is a risk because people's conditions might not be properly monitored, and their use of medication may not be appropriately controlled.

Inspector's evidence

There was step-free entrance to the pharmacy which allowed access to people with mobility difficulties and wheelchair users. Due to the additional workload and restrictions cause by the pandemic, some of the services, which were usually provided, such as medicine use reviews (MURs) and travel vaccinations, had been temporarily stopped. There was a small range of healthcare leaflets and a site used for health promotional activities.

The pharmacy received most of its prescriptions via the electronic prescription service (EPS) and there was a home delivery service. The number of deliveries had increased significantly but the workload was being adequately managed by the regular delivery driver, who was working full-time. The delivery service had been adapted to minimise contact with recipients, and the delivery driver wore a face mask.

Space was quite limited in the dispensary, but the workflow was organised into separate dispensing areas and a designated checking area. The dispensary shelves were reasonably well organised, neat and tidy. Dispensed by and checked by boxes were initialled on the medication labels to provide an audit trail. Baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. Some baskets containing assembled prescriptions were stored on the floor, which was unhygienic and risked contamination and physical damage to medicines. The SI said he would address this issue when the risk was pointed out.

The pharmacy had written procedures for dispensing high-risk medicines such as anticoagulants, methotrexate, lithium and insulin. There was a poster on display in the dispensary reminding the team of the need of a valproate pregnancy prevention programme for people in the at-risk group, and to ensure they were given the appropriate information and counselling.

A high number of people received their mediation in multi-compartment compliance aid packs and the pharmacy had continued to provide this service throughout the pandemic. There was a SOP for this process and the trainee dispenser confirmed that the packs were always assembled against a current prescription and labelled at the time of assembly. The medicine descriptions were usually included on the packaging to enable identification of the individual medicines. Disposable equipment was used to reduce the risk of contamination.

The pharmacy had a 'Support for self-care' SOP to help the pharmacy team sell OTC medicines to people. Codeine linctus was listed as a red flag product in this SOP, indicating requests should be referred to the pharmacist. Members of the pharmacy team confirmed that they followed this procedure and said they referred requests for codeine products to the RP. The trainee MCA explained

what questions she asked when making a medicine sale and when to refer the person to a pharmacist. She explained that she would refer to the RP if the request was for codeine linctus, but she usually recommended a different product, if someone had a dry cough. Another member of the team said she referred any requests for codeine linctus to the RP, and if any of the staff asked her about codeine linctus, she would direct them to the RP. Members of the pharmacy team confirmed that both the SI and the other regular pharmacist sold codeine linctus but sometimes refused sales. The SI said before selling codeine linctus he would always ask the person what it was used for, and if it was for a dry cough, he would sell it. He said he did not specifically recommend it, and would usually suggest another product, if codeine wasn't asked for by name.

CDs were stored in two CD cabinets which were securely fixed to the wall. Pharmacy medicines were stored behind the medicine counter so that sales could be controlled. There were 39 bottles of 200ml codeine linctus in the pharmacy on the shelves behind the medicine counter. They were out of reach and sight of the public. Phenergan Elixir, which was also addictive and liable to misuse, was stored in this location too. Recognised licensed wholesalers were used to obtain medicines. The SI confirmed that the pharmacy did not supply any other pharmacy with medicines and did not have a Wholesale Dealer's Licence.

Routine date checking was carried out and documented. Around thirty containers were seen on the dispensary shelves and in a basket in the compliance aid area, containing medicines which had been removed from their original containers. Some of these had not been labelled appropriately and did not contain expiry dates or batch number. This was not in line with regulations and there was a risk that date expired medicines may be supplied in error. The SI removed these from the shelves, when this risk was pointed out, and he said they would not be used. Patient returned medicines were stored in the basement. There was some current stock in close proximity to the returned medicines, so there was a risk that they could become mixed up. The SI confirmed he would separate these.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

Members of the pharmacy team have the equipment and facilities they need for the services they provide. They maintain the equipment so that it is safe and use it in a way that protects privacy.

Inspector's evidence

A recent version of the British National Formulary (BNF) was available and the pharmacist could access the internet for the most up-to-date information. There was a clean medical fridge in the consultation room, which was convenient for the travel and flu vaccination service. All electrical equipment appeared to be in good working order.

There was a selection of clean glass liquid measures. Separate measures were available for measuring controlled drug solutions. Some empty medicine containers were being stored uncapped in the basement which risked contamination. The SI confirmed he would address this issue when the risk was pointed out. Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. PMRs were password protected.

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.	