General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Audenshaw Pharmacy, 3 Chapel Street, Audenshaw, MANCHESTER, Lancashire, M34 5DE

Pharmacy reference: 1033494

Type of pharmacy: Community

Date of inspection: 04/11/2020

Pharmacy context

This busy community pharmacy is located in a parade of shops in a residential area. Most people who use the pharmacy are from the local area. The pharmacy dispenses mainly NHS prescriptions and 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 (OTC) medicines. This was an intelligence-led inspection based on information received by the GPhC that the pharmacy had been obtaining unusually large quantities of codeine linctus, which is liable to abuse and misuse. The inspection was undertaken during the Covid 19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; 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 the risks when selling pharmacy medicines which are liable to abuse and misuse.
		1.2	Standard not met	The pharmacy does not have adequate systems in place to review and monitor the sales of codeine linctus which is liable to abuse and misuse.
2. Staff	Standards not all met	2.2	Standard not met	Some members of the pharmacy team are not qualified or appropriately trained for the activities they carry out.
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 the risks in relation to the sales of codeine linctus and other pharmacy medicines liable to abuse and misuse. This means that there are some risks to patient safety and vulnerable people might be able to obtain medicines that could cause them harm. The pharmacy's working practices in relation to other services, including the supply of prescriptions, are generally safe. 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 and roles and responsibilities were set out in the SOPs. There were signatures showing that some members of the pharmacy team had read and accepted the SOPs, but newer members of the team had not read them, so there was a risk that they might not fully understand the pharmacy's procedures or their personal responsibilities. Some members of the team were not wearing uniforms or anything to indicate their role, so this might be confusing to people visiting the pharmacy.

The pharmacy superintendent (SI), who was also one of the company directors, was working as the responsible pharmacist (RP). His name was displayed as per the RP regulations. He worked most days in the pharmacy although he had taken a three-week absence in February and March 2020. The SI said the demand for codeine linctus over-the-counter (OTC) started to increase around this time, and when he returned to work, the team had raised concerns about the increasing number of requests for codeine linctus. During team discussions over the next few weeks, it became evident that the pharmacy was being targeted by a group of people who were using different clothing and disguises in order to obtain additional supplies. They also believed the same group were asking local people to come into the pharmacy to buy codeine linctus, and occasionally Phenergan liquid, on their behalf. The SI estimated that the pharmacy was selling around 30 bottles of codeine linctus each week at this time. During that period, he said there had been many challenges due to the pandemic; he was working long hours in the pharmacy often after it was closed, they were having staff issues, the team was struggling to obtain stock of some medicines, and the local GP's closed door policy meant the pharmacy was getting many more queries from patients needing help and advice. He admitted he was distracted by this and he had not realised the extent of the codeine linctus problem until around July 2020, when he had taken action to address it. He spoke to the person who he believed was the group leader and asked why they were buying so much. When he didn't receive a plausible answer, the SI told the person that he would not sell members of the group anymore codeine linctus, and he believed they had stopped coming in after this. The SI had not reported the matter to the police, and he did not alert the local police CD liaison officer, the CD accountable officer or any other pharmacies in the area to the group's activities. As part of the action taken to address the problem in the pharmacy, he moved the codeine linctus out of public view and increased the price from £2.85 to £4.99 in an attempt to reduce sales. He also told the staff to check with him if they thought anyone was requesting it too often.

There was a written protocol on selling medicines and giving advice, however this had not been reviewed in light of this incident. Staff signatures indicated they had not read it since 2016, and newer

members of the pharmacy team had not seen it. The protocol stated that people using medicines regularly should be referred to the pharmacist and they should be aware of requests for sedatives and medicines with a common ingredient, such as codeine. There wasn't a SOP for OTC sales, other than for children's cough and cold remedies. A risk assessment had not been completed for the sale of medicines liable to abuse and misuse. And despite the relatively high number of requests, there was nothing in place to record the sales or refusal of sales for codeine linctus or other medicines liable to abuse such as Phenergan. This was a risk as there was no way of capturing and sharing information with other members of the pharmacy team. The SI estimated that they were now selling around ten bottles of codeine linctus each week and team members thought that they sold codeine linctus on a regular basis to around six individuals. The SI did not think they had a problem with Phenergan as they hadn't sold any for weeks. At the end of the inspection, the SI told the inspector that he had decided to stop selling codeine linctus in the pharmacy. He said he would prepare a new SOP for OTC medicines and do a risk assessment of all P medicines liable to abuse and go through it with the pharmacy team. He sent copies of these to the inspector a few days after the inspection.

The SI had considered the risks of coronavirus for the pharmacy team and people using the pharmacy. He had introduced several steps to ensure social distancing and infection control. There were information notices about Covid-19 on display advising people with symptoms to stay out of the pharmacy and reminders to those entering of the requirement to maintain social distancing. The SI was part of a Primary Care Network group as well as a group of local pharmacists, who shared information and helped each other out, so he felt reasonably well supported. A business continuity plan was in place with guidance and emergency contact numbers to use in the case of systems failures and disruption to services.

There was a complaint procedure and the results of the 2018/2019 customer satisfaction survey were available on www.NHS.uk website. Results indicated 86% of respondents rated the pharmacy very good or excellent. The RP record was completed daily, but the RP did not usually record the time they ceased their duties, which might make it harder to identify who was responsible if there were any queries or problems. Confidentiality was discussed with team members as part of their induction and they were required to sign confidentiality clauses. Assembled prescriptions and paperwork containing patient confidential information were stored appropriately, so that people's details could not be seen by members of the public. The SI and second pharmacist had completed the Centre for Pharmacy Postgraduate Education (CPPE) level 2 training on safeguarding. The contact details of who to report safeguarding concerns to in the local area were available.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy has enough staff to manage its workload. But training is not well organised, and some members of the team are doing tasks that they aren't trained or qualified to do. Whilst the pharmacy team has opportunities to discuss issues informally, these communications are not usually recorded, so the pharmacy may not always be quick to act on any issues raised.

Inspector's evidence

There were two pharmacists (the SI and a second pharmacist), two NVQ2 qualified dispensers (or equivalent) who had both worked at the pharmacy for around six years, and three new untrained members of staff working at the time of the inspection. 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 people who visited the pharmacy. Absences were covered by re-arranging the staff hours. The second pharmacist regularly worked at the pharmacy one and a half days each week providing support to the SI. He was only occasionally the responsible pharmacist. His main role was checking compliance aid packs and he was rarely involved in supervising counter sales.

The pharmacy had a high turnover of staff and a qualified member of the team had recently started a maternity leave. The team had staffing issues caused by Covid-19 when three members of the team had been required to self -isolate, and there were challenges recruiting and retaining staff. The pharmacy team were not currently completing any structured training and they did not have protected training time. One of the three new members of staff had worked at the pharmacy for four weeks, one had worked for three months and one had worked for six and a half months. None of these new staff members had read the SOPs or been enrolled onto accredited training courses. The SI said because of the extra workload caused by the pandemic and difficulties with staffing, he did not think it was appropriate for them to start training courses. He had told the member of staff who had worked at the pharmacy for six and a half months that she would be enrolled onto a course in January 2021. New staff were given information to read and had coaching on tasks from senior staff. And any dispensing they carried out was checked by a qualified dispenser before the pharmacist made a final check. There was an induction checklist, but the completion of this had not been recorded for any of the new staff. The SI confirmed that new staff attended an evening training session within the induction period which covered an overview of confidentiality, SOPs, clinical governance, information governance, audits and improvement. Pharmacy team members received positive and negative feedback informally from the SI and discussed their performance and development with him during their probation periods.

Informal team meetings were held where a variety of issues were discussed, such as concerns about the high volumes of codeine linctus being requested. However, actions taken in response to concerns were not recorded and although concerns could be raised openly, they were not documented, so might not always be addressed. The second pharmacist said he felt empowered to exercise his professional judgement and could comply with his own professional and legal obligations. For example, refusing to sell codeine linctus if he didn't feel it was appropriate. He said he was not under any pressure from anyone to sell codeine linctus.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises generally provide a professional environment for people to receive healthcare services. The pharmacy has a private consultation room that enables it to provide members of the public with the opportunity to have confidential conversations.

Inspector's evidence

The pharmacy premises, including the shop front and facia, were reasonably clean and in an adequate state of repair. The retail area was free from obstructions and professional in appearance. The temperature and lighting were adequately controlled. Staff facilities were limited to a tiny kitchen area and a WC. There was a wash hand basin in the staff area and hand sanitizer gel was available. There was a separate dispensary sink for medicines preparation with hot and cold running water. There was a consultation room available for people who needed a private area to talk. But it was also used as an office, so it contained paperwork and was cluttered, which compromised the professional image.

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

Summary findings

The pharmacy orders unusually large amounts of codeine linctus, but it cannot demonstrate that suitable safeguards are in place to make sure sales are safe and appropriate. This is a patient safety risk because people's conditions might not be properly monitored, and their use of medication may not be appropriately controlled. The pharmacy offers a range of other healthcare services, which are generally well managed, so people receive appropriate care. It gets its medicines from licensed suppliers and the team carries out some checks to ensure medicines are in suitable condition to supply.

Inspector's evidence

There was a step up to the front door of the pharmacy, but customers with prams and wheelchair were offered assistance when entering the pharmacy. Staff would always be ready to serve customers at the door if necessary. Services provided by the pharmacy were advertised and the pharmacy team were clear what services were offered. Signposting information was available in the pharmacy to direct people to services elsewhere if necessary. The SI spoke Gujarati which assisted some of the non-English speaking people in the local community. There was a home delivery service with associated audit trail. The service had been adapted to minimise contact with recipients, in light of the coronavirus pandemic. Space was very limited in the dispensary. Baskets were used to improve the organisation in the dispensary and prevent prescriptions becoming mixed up. The baskets were stacked to make more bench space available.

The pharmacy team asked the 'WWHAM' questions when selling pharmacy (P) medicines. The pharmacists and other members of the pharmacy team did not recommend codeine linctus and suggested alternative cough mixtures when asked for it. They only sold codeine linctus for dry coughs and they did not sell more than one bottle at a time. Team members sometimes used the excuse 'it's not in stock', if they wanted to refuse the sale, but found this difficult and felt intimidated at times. The SI said the team knew to refer requests for codeine linctus to him, if they thought the person was buying it too often. Members of the pharmacy team who worked on the medicine counter confirmed that they did refer requests for codeine linctus to the pharmacist if people requested more than one or two bottles each week. They described around six people who regularly requested and bought codeine linctus from the pharmacy. One elderly person bought two bottles each month for a dry tickly cough. Another person requested a bottle nearly every day and had been allowed one or two each week for around three or four months. This person often bought Sominex at the same time which contains the sedative diphenhydramine, and is known to be misused. One member of the pharmacy team believed that one of the people who requested codeine linctus regularly was misusing it because their face looked grey. They described another person and their partner who both bought codeine linctus regularly. Another person had been sold one bottle a week for around a year and the SI believed he might be using it for pain relief. The SI said he had told this person that codeine linctus was addictive and he should go to his GP, but he continued to sell it to him. The SI said these people did not have prescriptions dispensed at the pharmacy and he did not know their names. He had not signposting anyone to a local drug and alcohol misuse service for help with addiction.

A large number of people received their medication in multi-compartment compliance aid packs. Some people had been transferred onto original pack dispensing where appropriate, but a significant number

of people were continuing to receive their medication in compliance aid packs. Disposable systems were generally used to reduce the risk of contamination.

P medicines were stored behind the medicine counter so that sales could be controlled. The SI usually ordered OTC medicines, but discarded the list after ordering, so there weren't any records of what had been ordered, apart from the invoices. The SI said he ordered around forty 200ml bottles of codeine linctus in October but up to three times as many in earlier months when the group were purchasing it. There were four bottles of 200ml Pinewood codeine linctus on shelves between the medicine counter and dispensary. The SI explained that because of the increase in requests for codeine linctus he made the decision around July 2020 to put some other items in front of the codeine linctus, so it could not be seen by the public. In this way, if anyone decided to refuse the sale, they could tell the person requesting it, that they didn't have any in stock. This was to prevent people 'kicking off' when they were refused the sale. The SI confirmed that they occasionally received NHS prescriptions for codeine linctus and when he checked the PMR system there had been seven NHS prescriptions since January 2020. This accounted for around 4500ml, which the SI said had been dispensed from 2 litre stock bottles. There was a small amount left in a 2 litre stock bottle in the dispensary. They did not supply other pharmacies with codeine linctus stock.

Recognised licensed wholesalers were used to obtain medicines. No extemporaneous dispensing was carried out. Medicines were stored in their original containers at an appropriate temperature. Alerts and recalls were received via email messages from the NHS area team and the MHRA.

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

Team members routinely wore personal protective equipment (PPE) when working in the pharmacy, which consisted of face masks, aprons and gloves. Visors were also available. Team members had their temperature checked each day when they arrived at work. Only three customers were allowed into the pharmacy at any time. There were barriers to ensure adequate space in front of the medicine counter and there was a Perspex screen to help reduce the spread of infection.

The pharmacist could access the internet for the most up-to-date information. For example, the electronic BNF and medicines compendium (eMC) websites. There was a medical fridge and all electrical equipment appeared to be in good working order. Computer screens were positioned so that they weren't visible from the public areas of the pharmacy. Patient medication records (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.