

Registered pharmacy inspection report

Pharmacy Name: Audley Late Night Pharmacy, 114 -116 Audley Range, BLACKBURN, Lancashire, BB1 1TG

Pharmacy reference: 1100749

Type of pharmacy: Community

Date of inspection: 04/11/2020

Pharmacy context

This community pharmacy is in a large residential area close to the centre of Blackburn. The pharmacy's main activities are dispensing NHS prescriptions and selling over-the-counter medicines. The pharmacy supplies some medicines in multi-compartment compliance packs to help people take their medicines and it delivers medicines to some people's homes. This was a targeted inspection after the GPhC received information that the pharmacy had been obtaining an unusually large quantity of codeine linctus, which is addictive and liable to abuse and misuse. All aspects of the pharmacy were not inspected on this occasion. The inspection took place during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan

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 doesn't fully manage all the risks involving sales of codeine linctus. And it doesn't have ongoing checks to make sure the changes it makes fully reduce the risks to people taking a medicine that may cause them harm. The pharmacy doesn't provide pharmacists with information in its written procedures on how to suitably manage requests for 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 does not have the necessary ongoing safeguards in place to adequately manage the safe supply of codeine linctus which is a medicine liable to misuse.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy mostly identifies and manages the risks associated with its services, including the risks from COVID-19. But it doesn't fully manage all the risks for the sales of codeine linctus. The pharmacy doesn't continue its ongoing checks to make sure the changes it makes sufficiently reduce the risk of people obtaining medicines that could cause them harm. The pharmacy has up-to-date written procedures for the team members to follow to help ensure the pharmacy's services are provided safely. But these procedures do not give clear guidance for pharmacists to help intervene following requests to supply codeine linctus. The pharmacy team members respond appropriately when errors occur, they discuss what happened and they take appropriate action to prevent future mistakes.

Inspector's evidence

The pharmacy had a range of standard operating procedures (SOPs) that provided the team with information to perform tasks supporting the delivery of services. The SOPs described the roles and responsibilities of the team. The SOPs were last reviewed by the Superintendent Pharmacist (SI) in October 2020. Team members were in the process of reading the reviewed SOPs and signing the signature sheets to show they understood and would follow the SOPs. The team demonstrated a clear understanding of their roles and knew when to refer people to the pharmacist. The pharmacy had a sale of medicines protocol that was reviewed by the SI in October 2020.

The SI had identified from the invoices supplied by wholesalers a large volume of 200ml codeine linctus purchased by the pharmacy. The SI had also read the GPhC press release regarding the enforcement action taken against six pharmacies in relation to codeine linctus sales. The pharmacists and team members were aware that codeine linctus was liable to misuse and were concerned about the number of people requesting codeine linctus. In order to ascertain how frequently people asked for codeine linctus, how many requests for codeine linctus were refused and how many sales were made the SI developed a monitoring sheet for the team to record this information. The monitoring took place throughout September 2020 and the first five days in October 2020. After 05 October the SI had written on the sheet 'refuse sale to all unless the pharmacist says otherwise'. The pharmacy did not continue to monitor requests for codeine linctus after 05 October 2020. The staffing profile indicated that different pharmacists and team members worked at different times which would make it difficult to monitor repeat requests without an audit process such as the monitoring sheet. This meant there was a risk that repeat sales could take place without the proper checks. The SI and pharmacists would also not have information to know if requests for codeine linctus were still being made and refused which could provide them with opportunities to offer people requesting codeine linctus advice and support.

The reviewed sales of medicines protocol included a requirement that sales of codeine linctus must be personally managed by the pharmacist. The protocol did not provide guidance and advice for pharmacists on how to manage requests for codeine linctus. For example, there was no information such as signposting the person to an appropriate support organisation when the pharmacist refused a sale due to concerns about possible abuse of codeine linctus.

The pharmacy was inspected during the COVID-19 pandemic. The pharmacy had not undertaken individual risk assessments for each team member to identify their personal risk of catching the virus.

The pharmacy had a pandemic control SOP. The team members had access to Personal Protective Equipment (PPE) and wore face masks or face visors and gloves during the inspection. Team members wearing the face visors had their name printed on the bottom so people knew who they were talking to. Throughout the inspection the team members mostly worked at separate stations in the dispensary which provided some level of social distancing. The pharmacy had COVID-19 information posters at the entrance and it displayed separate posters reminding people to wear face coverings. The pharmacy housed a post office and it used a stand at the entrance from the street to ask people to keep to a maximum of two in the pharmacy and a maximum of two in the post office. Markings on the floor directed people where to stand to maintain social distancing requirements. The team kept a hand sanitiser on the pharmacy counter for people to use. The team had developed a list of temperatures in Celsius and Fahrenheit to provide people with information on normal body temperature readings and readings that indicated a fever.

On most occasions the pharmacist or accuracy checking technician (ACT) when checking dispensed prescriptions and spotting an error asked the team member involved to find and correct the error. The pharmacy kept records of these errors known as near misses. The near miss records looked at did not provide details of what had been prescribed and dispensed which would help the team to spot patterns. The entries in the near miss record did not capture the causative factors. And in the section describing the actions to prevent the same error happening again the details were limited to correcting or amending the error. This meant there was little evidence of individual reflection by the team member involved with the error. The pharmacy regularly reviewed the near miss records and discussed the outcome in the weekly team meetings. As a result of one review the team had used boxes to separate some medicines they identified were often picked in error. The boxes had the name and strength of the medicine written on. This helped to reduce the number of picking errors and to ensure the team put medicine stock on the correct place on the shelves.

The pharmacy had up-to-date indemnity insurance. A sample of records required by law such as the Responsible Pharmacist (RP) records and records for the receipt and supply of unlicensed products met legal requirements. The pharmacy had safeguarding procedures and team members had access to contact numbers for local safeguarding teams. The team responded well when safeguarding concerns arose.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has an experienced team with the qualifications and skills to support its services. Team members work well together and support each other in their day-to-day work, especially at times of increased workload. They frequently discuss ideas and they review their processes to enhance the delivery of the pharmacy's services. Pharmacy team members receive feedback on their performance and the pharmacy encourages them to complete ongoing training to support keeping their knowledge and skills up to date.

Inspector's evidence

The Superintendent Pharmacist (SI) and two regular pharmacists covered most of the opening hours. The pharmacy team mostly worked part time and consisted of two pharmacy pre-registration students, a pharmacy accuracy checking technician (ACT), one pharmacy technician, three qualified dispensers, a trainee dispenser and two medicines counter assistants. The pharmacy also employed two delivery drivers. At the time of the inspection the SI, the two pre-registration students, the ACT, the pharmacy technician, three qualified dispensers, and the trainee dispenser were on duty. Many of the team had worked together for several years and were known to people in the local community who used the pharmacy. During the pandemic the team had worked well together to ensure pharmacy services were not affected.

The team held weekly meetings to discuss matters such as dispensing errors and the impact on workload from the COVID-19 pandemic. The pharmacy provided the team with opportunities to complete more training and team members were presented with a range of training subjects to choose from. The team members received regular performance reviews and were given opportunities to develop their skills. The pharmacy technician had initially trained as a dispenser and had discussed becoming a pharmacy technician as part of their performance review. The pharmacy technician had been supported throughout the training by the pharmacists and a pharmacy technician who previously worked at the pharmacy.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy premises are clean, secure and sufficient for the services provided.

Inspector's evidence

The pharmacy was clean, tidy and hygienic. It had separate sinks for the preparation of medicines and hand washing. As part of the actions taken to reduce the risk of infection from the COVID-19 virus the team regularly cleaned the pharmacy throughout the day including touch points such as door handles. The team kept floor spaces clear to reduce the risk of trip hazards. The pharmacy had enough storage space for stock, assembled medicines and medical devices. The premises were secure and the pharmacy restricted access to the dispensary during the opening hours. The window displays detailed the opening times and the services offered. The pharmacy had a defined professional area and items for sale in this area were healthcare related.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy mostly has suitable processes to manage its services safely. But it does not have the necessary ongoing safeguards in place to adequately manage the safe supply of codeine linctus which is a medicinal product liable to abuse. This means the pharmacy cannot be sure people receive medicines that are safe for them to take. The pharmacy gets its medicines from reputable sources and it stores and manages its medicines correctly. The team carries out appropriate checks to make sure medicines are in good condition and suitable to supply.

Inspector's evidence

People using the pharmacy were able to easily access the premises and were mostly from the local area. Team members spoke various South Asian languages which helped to ensure people received the correct information, advice and medical treatments when requesting an over-the-counter (OTC) medicine.

The inspector discussed with the Superintendent Pharmacist (SI) the information the GPhC had received about the volume of codeine linctus purchased by the pharmacy. The SI agreed the pharmacy had purchased large volumes of codeine linctus. The team was aware of the potential for codeine linctus to be misused and had worked with the SI in September and October 2020 to monitor how many people asked to buy codeine linctus, how many 200ml bottles were sold and how often a request to buy was refused. The information from this monitoring process revealed a large number of requests were made. This resulted in the SI making the decision that all requests for codeine linctus should be referred to the pharmacist. The inspector spoke to a team member who was working on the pharmacy counter. The team member confirmed that requests for codeine linctus were referred to the pharmacist and was not aware of any sales in the previous few weeks. The team member explained when people asked for a treatment for a dry cough, she asked the appropriate questions and offered one of the products on the pharmacy shelf such as pholcodine linctus. The team member explained that the team monitored requests for other products liable to abuse and would speak to people when there were concerns about the frequency of purchases. The team member explained people understood why they were asked questions about their requests for these products and reported that no-one had showed hostility to the team when they were refused a sale.

At the time of the inspection there were no bottles of 200ml codeine linctus on the shelves behind the pharmacy counter or under the pharmacy counter. A small amount of 200ml codeine linctus was found in an area of the dispensary where the pharmacists were usually based. A team member attempting to access a 200ml bottle of codeine linctus would have to ask the pharmacist for it. This would prompt the pharmacist to ask what it was for and intervene in the request to buy codeine linctus. A large stock bottle of codeine linctus used for dispensing against prescriptions was found in the dispensary. The inspector looked through the invoices from the main wholesalers used by the pharmacy for October 2020 and found no evidence of purchases of codeine linctus.

The pharmacy did not continue to monitor the requests, refusals and sales of codeine linctus after 05 October 2020. The SI reported not selling any codeine linctus in recent weeks. However, without the information from continued monitoring the SI would not be aware of all requests for codeine linctus

and refusals to sell when not on duty. The SI described requests for codeine linctus and how the person usually stated it was for a dry cough or for someone else. The SI explained when people were refused their requests to buy codeine linctus, they accepted the fact and left the pharmacy. There had not been any aggressive behaviour. The SI thought people who were refused sales probably tried other local pharmacies but had not contacted the other pharmacies to discuss this with them. The SI was not aware of requests for Phenergan Elixir though had heard of the product Purple Drank. One of the regular pharmacists reported that the team actively tried to minimise sales by recommending other OTC products for cough and educating customers on the dangers of opiates. The sale of medicines protocol did not include guidance for pharmacists on how to manage requests for codeine linctus. And the advice to give to people when a sale was refused. This meant there was a risk of inconsistent advice and support being provided to people. And the SI may not know if all the pharmacists working at the pharmacy were responding appropriately to requests for codeine linctus.

The SI informed the inspector that the pharmacy occasionally supplied codeine linctus against NHS prescriptions and regularly against a private prescription. The SI had not spoken to people who presented prescriptions for codeine linctus and did not know why they had codeine linctus prescribed for them. The SI agreed this meant they would not know if the person needed advice and support or whether it was appropriate for the pharmacist to discuss the prescription with the prescriber.

The pharmacy provided multi-compartment compliance packs to help people take their medicines correctly. The ACT managed the service with support from others in the team. To manage the workload the preparation of the packs was divided across the month. The team usually ordered prescriptions for the packs in advance of supply. This allowed time to deal with issues such as missing items and the dispensing of the medication into the packs. The team used a dedicated section of the dispensary away from the distractions of the retail area to dispense and check the packs. The team recorded the descriptions of the products within the packs and supplied the manufacturer's patient information leaflets.

The pharmacy provided separate areas for labelling, dispensing and checking of prescriptions. The pharmacy team used baskets when dispensing to separate individual people's medicines and to help prevent them becoming mixed up. The pharmacy had checked by and dispensed by boxes on dispensing labels which recorded who in the team had dispensed and checked the prescription. A sample of completed prescriptions found the team completed both boxes. The team passed on information obtained from the person's electronic record to the pharmacist who was completing the clinical check of the prescription. This information included dose changes and new medicines. The pharmacist completed the clinical check before the prescription was dispensed. Once the medicine had been dispensed it was accuracy checked by the ACT. The pharmacy kept a record of the delivery of medicines to people. Due to COVID-19 the delivery driver did not ask people to sign for receipt of their medication. The driver left the medication on the person's doorstep before moving away to watch them pick-up the medication.

The pharmacy obtained medication from reputable sources. The pharmacy has a wholesale dealer licence (WDL). The SI explained no controlled drugs (CDs) including codeine were supplied via the WDL. The team members checked the expiry dates on medicines and kept a record of this activity. The team attached coloured dots to medicines with short expiry dates to prompt them to check the medicine was still in date. No out-of-date stock was found during the inspection. The team checked and recorded fridge temperatures each day and a sample of records found the temperatures were within the correct range. The pharmacy had medicinal waste bins to store out-of-date stock and patient returned medication.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment it needs to provide safe services and to protect people's private information.

Inspector's evidence

The pharmacy had references sources and access to the internet to provide the team with up-to-date clinical information. The pharmacy used a range of CE equipment to accurately measure liquid medication and it had a large fridge to store medicines kept at these temperatures.

The computers were password protected and access to people's records restricted by the NHS smart card system. The team positioned the dispensary computers in a way to prevent the disclosure of confidential information. The pharmacy stored completed prescriptions away from public view and it held other private information in the dispensary and rear areas, which had restricted access.

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.