General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Riaz Pharmacy, 112 Randal Street, BLACKBURN,

BB17LG

Pharmacy reference: 1117846

Type of pharmacy: Community

Date of inspection: 28/09/2020

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 medicine 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: 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 properly manage the risks and governance around the purchasing, sale, and supply of codeine linctus. So, vulnerable people may be able to obtain codeine linctus when it could cause them harm.
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 buys and sells large amounts of codeine linctus without adequate safeguards in place.
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 the risks associated with its services, especially in relation to the sale and supply of codeine linctus to people. This means that vulnerable people might be able to obtain medicines that could cause them harm. The pharmacy has written procedures that the pharmacy team follows but there is no evidence it reviews all these procedures regularly. This means there is a risk team members may not be following up-to-date procedures. The pharmacy completes all the records it needs to by law and people using the pharmacy services can raise concerns and provide feedback. The team members respond appropriately when errors occur, they discuss what happened and they take action to prevent similar errors.

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 2016 which meant there was a risk that team members were not following up-to-date procedures. Most team members had read the SOPs and signed 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 to the pharmacist.

The pharmacy had a medicines protocol to support the sale of over-the-counter medicines. The protocol did not include medicines that were liable to abuse such as codeine linctus. The protocol had a section entitled special restrictions but this only focused on medicines such as cold remedies containing pseudoephedrine. Each SOP folder had a list detailing the SOPs held within the folder. One folder had a list that included a SOP covering the sale of analgesics containing codeine and dihydrocodeine but the SOP was not in this folder or any of the other SOP folders. The pharmacist explained this SOP had been removed for review and three days after the inspection the pharmacist sent the inspector the reviewed SOP. The date of review was 01 October 2020 and had been reviewed by the pharmacist on duty at the time of the inspection. The SOP included an appendix dated 07 August 2020 reflecting the notice the pharmacist had developed to inform the team that the pharmacy held zero stock of stock of codeine linctus. It also detailed the steps to take when a person requested codeine linctus including referral to the pharmacist. The team members' signatures on the SOP signature sheet were dated on or after the date of the appendix of 07 August 2020. There were no signatures on the sheet following the review on 01 October 2020. The pharmacist and team members were aware that codeine linctus was liable to misuse and stated they were concerned about the number of people requesting codeine linctus. However, the pharmacy did not keep records of the sales of codeine linctus. And it didn't keep records of the refusal of requests to buy codeine linctus. This meant the pharmacy had no audit trails for the sales of codeine linctus. There was no documentation for the team to monitor the frequency people made purchases of codeine linctus by the same person and to monitor the number of requests that had been refused. The staffing profile indicated that different pharmacists and team members worked at different times making it difficult to monitor repeat sales without an audit process. The risk was repeat sales went ahead without the proper checks.

The pharmacy was inspected during the COVID-19 pandemic. The pharmacy had assessed each team member to identify their personal risk of catching the virus and the steps needed to support social

distancing and infection control. No records were kept of these risk assessments. The team members had access to Personal Protective Equipment (PPE) and wore face masks during the inspection. 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 entrances and it displayed separate posters reminding people to wear face coverings. The pharmacy had a clear plastic screen across part of the pharmacy counter to provide the team with additional protection. The outer edges of the screens were embedded with key messages relating to COVID-19 symptoms, social distancing requirements and infection control. At the height of the pandemic the pharmacy used the two entrances to create a one-way system for people to enter and leave the pharmacy.

On most occasions the pharmacist when checking dispensed prescriptions and spotting an error asked the team member involved to find and correct the error. The pharmacist discussed the error with the team member and common errors were shared amongst the team to learn from. The pharmacy kept records of these errors known as near misses. The near miss records looked at did not record details of what had been prescribed and dispensed which would help the team to spot patterns. The entries did not capture the causative factors and learning outcomes. The details recorded in the section to describe the actions to prevent the same error happening again were limited to statements that the error was corrected or amended. This meant there was little evidence of individual reflection by the team member involved with the error. The team had separated ramipril capsules and tablets after identifying they were often involved with near miss errors. The pharmacy had a system to report errors that reached the person, known as dispensing incidents. The pharmacist reported a recent incident involving a new driver who was not familiar with the area and had delivered to the wrong address. The team identified that the two people had similar names and addresses. The pharmacist reminded the driver to take their time when delivering and to always use the postcode. The team stored the deliveries for each day, in totes, in the order they would be delivered, based on the person's address. The pharmacy had a procedure for handling complaints raised by people using the pharmacy and it displayed information for people to know how to raise a concern. The pharmacy team used surveys to gather feedback from people and published the results on the NHS.uk website. Positive comments from the last survey were about the efficiency of the service provided by the team.

The pharmacy had up-to-date indemnity insurance. A sample of CD registers looked at met legal requirements. The pharmacy did not regularly check CD stock against the balance in the register to help spot errors such as missed entries. The pharmacy recorded CDs returned by people and promptly destroyed them. A sample of Responsible Pharmacist (RP) records looked at showed some entries did not have the time the RP stopped being on duty. Private prescription records looked at met legal requirements.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has a 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. They openly discuss errors so everyone can learn from them and improve their skills. The team members regularly discuss what they can improve on. And they agree new processes to help them efficiently deliver the pharmacy's services. But sometimes the changes the pharmacy makes are not always adequate, including changes in response to frequent requests for codeine linctus sales.

Inspector's evidence

The responsible pharmacist on duty at the time of the inspection worked full-time at the pharmacy. Four regular locum pharmacists covered the remaining opening hours. The pharmacy team comprised of three pharmacy students, a pharmacy accuracy checking technician, 13 qualified dispensers, two pharmacy apprentices, a new team member and two delivery drivers. Most team members worked part time. At the time of the inspection two qualified dispensers, two pharmacy apprentices and the new team member were on duty. The pharmacy provided opportunities for team members to undertake extra training and gave them some protected time at work to complete their training.

The team members received regular informal feedback on their performance and were given opportunities to develop their skills. The team members reported that the informal feedback had been very helpful during the early days of the pandemic when everyone in the team was managing increased workload and pressures. The team members were encouraged to give each other feedback or pass on comments to colleagues from people using the pharmacy. One of the dispensers had discussed pharmacy technician training with the regular pharmacist who agreed to enrol the dispenser on to the course. This dispenser had also enrolled on to a management training course whilst waiting for the pharmacy technician course to start.

The team held regular meetings and during the pandemic when some team members were furloughed Zoom meetings had been arranged to ensure everyone was kept up to date with developments. The team members also used a group chat facility to share issues and ideas. This group had been set up because team members worked different shifts and several team members may not see each other for some time. The team used the group meetings to identify ways of improving the delivery of pharmacy services and to discuss feedback from people using the pharmacy. The team had discussed the issue of stock shortages for several medicines and how to ensure medicines were available to supply. The team members found on some occasions their reliance on the auto-order system had led to low levels of stock on the shelves as it took some time for them to discover that the stock was not coming in from the wholesalers. To address this the team introduced a process of regularly checking stock levels and agreeing a point at which the number of packs remaining triggered an order.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is clean, secure and suitable for the services provided. It has facilities to meet the needs of people requiring privacy when using the pharmacy services.

Inspector's evidence

The pharmacy was clean, tidy and hygienic and had an infection control SOP. The team regularly cleaned the pharmacy throughout the day to reduce the risk of infection. The pharmacy had separate sinks for the preparation of medicines and hand washing. The pharmacy had space available for the team to have private conversations with people. The premises were secure and the pharmacy restricted access to the dispensary during the opening hours. 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 has processes that mostly support it to manage its services safely. But it does not have adequate safeguards in place to manage the safe supply of codeine linctus which is a medicinal product liable to abuse. It does not appropriately monitor and control its sales of codeine linctus. 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

Access into the pharmacy was via two entrances, one had a ramp with a handrail. People using the pharmacy were mostly from the local area and were predominantly people from South Asia. Team members spoke various South Asian languages and this helped to ensure people receive the correct information, advice and medical treatments when requesting an over-the-counter (OTC) medicine.

The pharmacy had a sales of medicines protocol but this did not include medicines liable to abuse such as codeine linctus. The pharmacist on duty during the inspection agreed large quantities of codeine linctus had been purchased by the pharmacy and the pharmacy had been selling around four to five bottles of 200ml codeine linctus a day. The pharmacist knew codeine linctus was a medicine liable to abuse. The pharmacy did not monitor the trend in sales of codeine linctus and when requests to buy codeine linctus were refused. This meant the pharmacist and other pharmacists working at the pharmacy could not be confident the person requesting the codeine linctus had not purchased it before or was previously refused a request. The pharmacist stated the pharmacy had stopped purchasing codeine linctus in July 2020. The pharmacist explained since the COVID-19 pandemic he had seen an increase in requests for codeine linctus and he had noticed a large amount of codeine linctus 200ml bottles in stock in the upstairs storeroom in the pharmacy. The pharmacist explained the pharmacy ordering system triggered an order each time a sale took place. The pharmacist had discussed with the pharmacy team the volume of codeine linctus sold which resulted in a decision to stop selling it. The pharmacist explained that NHS prescriptions for codeine linctus were very rare and records of private prescription supplies looked at during the inspection found no evidence of codeine linctus supplies having been made against private prescriptions. No large stock bottles of codeine linctus were found in the pharmacy. The pharmacist had produced a notice for the team to refer to when people requested codeine linctus. One of these notices was attached to the wall of the dispensary and another notice was attached to the pharmacy counter only seen by team members. The notice stated that due to MHRA guidelines the stock of codeine linctus was reduced to zero. The notice informed the team members when a patient required codeine linctus, they must follow the procedure and pay particular attention to COVID-19 symptoms. The notice advised the team of suitable alternatives and if the patient was having difficulties with the use of codeine linctus to refer to the pharmacist on duty. The inspector spoke to a team member who explained when people asked to buy codeine linctus, she would follow the procedures and offer alternatives such as simple linctus. If the person refused the alternative product and wanted codeine linctus, she would ask the pharmacist to speak to the person. The team member stated that the team was never directly involved with the sale of codeine linctus, it was always the pharmacists who made the sale.

The pharmacy provided multi-compartment compliance packs to help around 200 people take their medicines correctly and to people living in five residential support settings. To manage the workload the team worked three weeks in advance of supply. This allowed time to deal with issues such as missing prescriptions and dispensing the medication into the packs. The team used a section of the dispensary to dispense the medication into the packs. The team used coloured baskets to prioritise the dispensing and checking of the packs. The team had introduced this system to help manage the occasions when there was a delay with receipt of some people's prescriptions from the surgery team. The team recorded the descriptions of the products within the packs to help people identify their medicines and it supplied the manufacturer's information leaflets. The pharmacy occasionally received copies of hospital discharge summaries which the team checked for changes or new items. The teams from the residential support settings sent the pharmacy team the medication list for each person. The list detailed the person's medication, dose and dose times and included information such as medicines supplied directly by the hospital. The pharmacy usually supplied some medicines as supervised and unsupervised doses to people accessing the substance misuse service. Due to the COVID-19 pandemic and the risk of infection most people had moved to collection only doses. The team prepared the doses in advance to reduce the pressure of preparing at the time the person presented. When the person received a supervised dose, the team handed the medication over whilst wearing disposable gloves.

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 looked at found that the team completed both boxes.

The pharmacy obtained medication from reputable sources. The team members checked the expiry dates on medicines and attached coloured dots to medicines with short expiry dates to prompt them to check the medicine was still in date. The team kept a list of medicines due to go out of date each month, no out-of-date stock was found during the inspection. The team checked the fridge temperatures but only recorded the daily readings for one of the two fridges. The fridge temperature records looked at were within the correct range. During the inspection the pharmacist added the second fridge to the computer for the team to add the temperature readings. The team members recorded the date of opening on liquids to help them identify products with a short shelf life once opened and check they were safe to supply. The pharmacy had medicinal waste bins to store out-of-date stock and patient returned medication. The pharmacy had equipment installed and a computer software update to meet the requirements of the Falsified Medicines Directive (FMD) but the team was not using the equipment.

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 had two fridges 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 pharmacy was open plan with the dispensary leading directly from the retail area. 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.	