## General Pharmaceutical Council

# Registered pharmacy inspection report

Pharmacy Name: Cryers Chemist, 1 Kenneth Street, ROTHERHAM,

South Yorkshire, S65 1AB

Pharmacy reference: 1039223

Type of pharmacy: Community

Date of inspection: 05/10/2020

## **Pharmacy context**

This community pharmacy is on a quiet street close to Rotherham town centre. The pharmacy's main activities are dispensing NHS prescriptions and selling over-the-counter medicines. The pharmacy provides some substance misuse services and it offers a medicine delivery service to people who are housebound. This was an intelligence-led 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. The inspection took place 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 properly manage the risks and governance around the purchasing, sale, and supply of codeine linctus. And it doesn't identify the risks and requirements involving the preparing, sale and supply of preparations containing codeine linctus. This means vulnerable people can 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. It does not manage the sales of codeine linctus and preparations containing codeine linctus safely.
		4.3	Standard not met	The pharmacy does not store all required medicines in accordance with The Misuse of Drugs (Safe Custody) Regulations 1973.
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. In particular, it does not have appropriate processes in place to safely govern the sale and supply of codeine linctus containing medicines, which can be misused. And it does not adhere to legal requirements of making, selling and supplying its own preparations containing codeine linctus. This means vulnerable people can obtain medicines that may cause them harm. The pharmacy has written procedures to support its team members in delivering its services and team members follow these procedures. They share learning about their mistakes and this helps to reduce the likelihood of similar mistakes occurring. The pharmacy keeps most records as required by law. People using the pharmacy services can raise concerns and provide feedback. Team members are knowledgeable about their role in safeguarding and act to help keep vulnerable people safe.

#### Inspector's evidence

The pharmacy was inspected during the COVID-19 pandemic. It had addressed risks associated with providing pharmacy services during the pandemic. But the owner had not completed a written COVID-19 risk assessment. Team members discussed and demonstrated the processes they had put in place to help manage services safely during the pandemic. This had included removing some traditional confectionary items such as cough sweets from sale, due to the risks associated with weighing and handling the sweets. The pharmacy had reviewed access to the premises and increase the frequency of cleaning tasks. All team members wore type IIR face masks routinely when working, and supplies of additional personal protective equipment (PPE) were available.

The pharmacy had a range of standard operating procedures (SOPs) to support its team members in delivering the pharmacy's services. SOPs covered responsible pharmacist (RP) requirements, pharmacy services and controlled drug (CD) management. These were due for review as the last documented review date was June 2018. This review had been undertaken by a pharmacist who provided regular support to the team. There was evidence of dated and signed amendments made to SOPs during the last review. A training record attached to individual SOPs confirmed team members had read and signed SOPs applicable to their role. And the dispenser on duty discussed different aspects of her role and was seen working in accordance with dispensary SOPs throughout the inspection.

The pharmacy had a protocol relating to the sale of over-the-counter medicines. The protocol covered the questions team members would ask, but did not provide specific details of how to manage medicines subject to abuse or misuse. A handwritten protocol at the medicine counter provided more information relating to managing requests for over-the-counter medicines. The protocol included a list of 'red-card substances' which required specific referral to the RP. The list included some medicines that had historically changed from Prescription Only Medicine (POM) to Pharmacy (P) medicine status, so the content of the protocol was out of date. It also contained a list of medicines liable to abuse or misuse, but codeine linctus was not included on this list. The RP, who was the pharmacy owner confirmed he regularly sold codeine linctus and provided details of a nostrum he made onsite using codeine linctus and simple linctus. Some labels associated with a batch of this nostrum indicated it was labelled as '200 mixture, one spoonful every three hours', this meant people purchasing the nostrum may not be aware of the ingredients of the mixture. And the risks associated with driving after taking

the medicine, or of becoming addicted to the medicine. The RP confirmed that codeine linctus sales were not monitored for trends and repeat sales. Records were not kept of the sales of codeine linctus or of the nostrum and the RP had not refused any sales to his knowledge. This meant the pharmacy had no audit trails relating to the frequency of sales or requests made by the same person for either codeine linctus or the nostrum.

SOPs covered near miss error reporting and dispensing incident reporting. The team explained the pharmacist would feedback to the team member involved in a mistake, and details of near miss errors would be recorded on a record in the dispensary. Team members felt they made an effort to record near miss errors when they happened, the most recent near miss recorded had occurred in June 2020. Team members could demonstrate actions they took to help reduce mistakes. For example, some shelves in the dispensary were clearly labelled to help inform staff of the correct stock locations for different medicines. And some medicines were stored in baskets on the shelves to reduce the risk of them becoming mixed up with other items. The pharmacy dispensed a relatively low number of NHS items, and most prescriptions were for repeat items. This helped team members to manage workload which reduced pressure during the dispensing process. There was separate bench space for labelling, assembling and checking medicines. And higher risk tasks relating to CDs were managed in a designated space to one side of the dispensary.

The pharmacy had a comprehensive guide to customer service and managing feedback. There was a process in place for people to raise a concern about the pharmacy or one of its services if required. And the owner addressed any concerns. The team on duty explained feedback throughout the pandemic had been largely positive. The pharmacy had intervened by raising concerns relating to vulnerable people a couple of times during the pandemic. It had contact details of safeguarding agencies and key workers available and team members confidently explained how they would manage and report a safeguarding concern to help ensure people's safety and wellbeing were maintained.

The pharmacy had up-to-date indemnity insurance, public and employer liability insurance arrangements. It also displayed details of its registration status with the Information Commissioners Office (ICO). Team members were aware of the need to maintain the confidentiality of people accessing pharmacy services. The pharmacy stored all personal identifiable information in staff only areas of the premises. And it had arrangements in place to dispose of confidential waste securely.

A sample of the controlled drug (CD) register looked at met legal requirements. The register contained running balances of CDs but these were not checked regularly against physical stock. The RP notice displayed contained the correct details of the RP on duty. But the RP had made one continuous entry into the RP register to document his role as RP between March and September 2020. And he confirmed he had been the only RP during the pandemic. The RP had failed to sign back into the register again following this declaration, so there were missing entries from September 2020. A discussion took place about this omission and the need to keep accurate and up-to-date records. The RP began to update the register and confirmed he would be signing in and out each day moving forward.

## Principle 2 - Staffing ✓ Standards met

#### **Summary findings**

The pharmacy has enough, suitably skilled team members to manage its workload. Team members work well together to support each other. They understand how to provide feedback about the pharmacy and how to raise a professional concern if needed.

## Inspector's evidence

The pharmacy team consisted of the RP, four part-time qualified dispensers and an additional team member who had begun work during the pandemic. This team member was providing administration support to the team. A discussion took place about the GPhC's recently updated guidance relating to the education and training requirements for pharmacy support staff. The RP and a dispenser were the only members of the pharmacy team on duty throughout the inspection. The RP undertook the pharmacy's medicine delivery service after closing. The owner had acted as RP every day since the beginning of the pandemic. He explained prior to the pandemic, two regular locums provided some cover. One of the regular locums continued to provide support at a distance. For example, supporting with some clinical governance requirements. The pharmacy displayed the details of the team members dispensing qualifications. The dispenser confirmed there was some access to continual learning through discussion and reading. The RP had attended a learning meeting relating to substance misuse services shortly before the pandemic started.

There was a whistle blowing policy and team members were encouraged to provide feedback openly. They enjoyed a positive working relationship with each other and many members of the team had worked together for a good number of years. Information was shared through informal conversations and through brief notes left between shifts. All team members had been working between 3 and 16 hours each week. The pharmacy had not undertaken formalised individual COVID-19 risk assessments with team members. But some team members considered vulnerable had been furloughed at the beginning of the pandemic, and they had received full support as and when they returned to work. This support had included discussions about risk management.

## Principle 3 - Premises ✓ Standards met

#### **Summary findings**

The pharmacy is clean, secure and suitable for the services provided. It has facilities to allow people to have a private conversation with a member of the pharmacy team.

### Inspector's evidence

The pharmacy was secure and maintained to a respectable standard. It was clean and working areas were kept in an orderly manner. The pharmacy had acted to manage the risks associated with social distancing. A heavy duty plastic curtain was in place across the full length of the medicine counter. And notices advised people to stand away from this area. Windows leading from the dispensary to the public area had been covered with Perspex, each had a small section cut out to allow team members to speak to people visiting the pharmacy. Members of the pharmacy team had access to hand washing facilities and hand sanitiser to support the enhanced infection control measures.

A storeroom on the first-floor level of the premises was cluttered with items such as historic invoices, old shelving and some older, out-of-date medicines. There was a clear path through the room. The medicines did not risk being mixed up with other stock and were stored on specific shelves. But there was no required need to keep them for any longer than necessary. The first-floor level also provided access to staff kitchen and toilet facilities. The pharmacy had a semi-private area to the side of the dispensary and this was in use throughout the inspection. It had a small consultation room situated between the medicine counter and dispensary. This was not in routine use during the pandemic. There was very rarely more than one person in the public area of the pharmacy, this meant team members could consult with most people on a one-to-one basis.

## Principle 4 - Services Standards not all met

#### **Summary findings**

The pharmacy has procedures which mostly help the team manage and deliver its services safely. But it does not have adequate safeguards to manage the safe supply of codeine linctus, which is a medicine liable to abuse and misuse. It does not appropriately monitor and control the sales of codeine linctus and codeine linctus containing medicines. This means people receive medicines that may not be safe for them to take. It obtains its medicines from reputable sources. But it does not always store some higher risk medicines in accordance with legal requirements. The pharmacy's services are easily accessible to people.

#### Inspector's evidence

People accessed the pharmacy via a slope or steps from street level. A separate entrance provided access to an area with a semi-private hatch which led into the dispensary. A notice on the main pharmacy door reminded people to wear a face covering when entering the pharmacy. Team members were knowledgeable about local signposting arrangements in the event the pharmacy couldn't provide a medicine or service.

The RP counselled people taking higher risk medicines. And observations made during the inspection included counselling provided to a person prescribed multiple medicines to manage pain, and over-the-counter counselling associated with a purchase of codeine based painkillers. The RP also advised this person that the medicine was designed for short term use only. Team members also had an awareness of other higher risk medicines and information about the valproate Pregnancy Prevention Programme (PPP) was available to issue to people at the point of dispensing.

The pharmacy supplied some medicines as supervised and unsupervised doses. To help manage the risk associated with COVID-19 during the pandemic some people had changed the frequency of attendance for these medicines, moving from supervised doses to collection at scheduled intervals. The team prepared collection doses in advance to reduce the pressure of preparing at the time the person presented. The RP was aware of how to raise any concerns he had relating to people using this service and had up-to-date contact information for the local substance misuse team.

The dispenser explained the hand-written protocol at the medicine counter was available to refer to when managing requests for over-the-counter medicines. The dispenser discussed applying WWHAM questioning techniques when managing a request for a P medicine, and explained these requests were brought to the attention of the pharmacist. The RP confirmed he personally managed all requests for codeine linctus. The RP was aware that requests for codeine linctus had raised considerably in the last few years and he explained he assumed the pharmacy was the only one in Rotherham selling it. The RP also explained that he thought requests had reduced in recent months. Both the RP and dispenser explained people asked for codeine linctus by name and information established during a conversation with the person making the request included asking what the person was using it for. Team members explained they were always informed it was for a dry cough, or people were buying it for a relative with a dry cough. The RP was aware that codeine linctus was a medicine liable to abuse and discussed the details of several conversations that had taken place, one with another local pharmacist and one with a team member about the abuse potential of the medicine. He explained he had considered this

information but had not put steps in place to monitor requests. The RP and dispenser confirmed some sales were to repeat customers, but felt most were made to people they did not know. The dispenser explained team members would leave notes of repeat requests for over-the-counter medicines to help share information with each other, these were discarded once team members had read the note. There were no notes present on the day of the inspection and the team explained there had not been any recent repeat requests made.

The RP confirmed the pharmacy had not dispensed an NHS or private prescription for codeine linctus for some time. And records from the patient medication record (PMR) system showed no dispensing in the last 90 days. The RP stated he used larger bottles of codeine linctus to make and sell his own cough mixture, and had been doing so for a number of years. The RP explained requests for the mixture were received from people who had taken it before, or who had it recommended to them by friends or family. The pharmacy did not record sales of the mixture. But some labels associated with the mixture had been produced on 18 September 2020. This activity 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 P medicine to that of POM.

The pharmacy obtained medicines from licensed wholesalers and some invoices relating to purchases made were kept onsite. A range of P medicines were stored behind the medicine counter. Codeine linctus was not stored at the medicine counter and was not advertised in anyway. Medicines in the dispensary were stored in an orderly manner. There was a date checking record in place to assist the team in ensuring medicines were safe and fit to supply. A random check of stock did find an out-of-date medicine, this was brought to the immediate attention of the RP. The team did check expiry dates during the dispensing process to further safeguard an out-of-date medicine being supplied.

The pharmacy had a secure cabinet to store medicines subject to safe custody regulation. But the cabinet was not a sufficient size to hold all stock of these medicines. Most medicines stored within the cabinet were out-of-date, a discussion took place about the need to request an authorised witness visit through the online CD reporting tool. The pharmacy stored medicines subject to cold chain requirements safely in a pharmaceutical refrigerator. The fridge was operating between two and eight degrees Celsius as required on the day of the inspection, but there were some gaps in temperature records noted. This meant it could be more difficult for the pharmacy to demonstrate the fridge was operating within the required temperature range at all times.

The pharmacy had medicinal waste bins to store out-of-date stock and patient returned medication. It also had some CD denaturing kits available. But the RP acknowledged waste receptacles for liquid waste and sharps were also required as the pharmacy had waste of these products requiring the specialist waste bins. The RP was signposted to organisations which may be able to support with this. The pharmacy kept these waste medicines and sharps separate to stock.

## Principle 5 - Equipment and facilities ✓ Standards met

#### **Summary findings**

The pharmacy has a suitable range of equipment to support the delivery of its services. Members of the pharmacy team use the equipment and facilities in a way which protects people's privacy.

#### Inspector's evidence

The pharmacy had a range of clean equipment available to support the delivery of pharmacy services. Equipment included crown stamped measuring cylinders for measuring liquid medicines. It had separate cylinders for use solely with methadone, and some single-use consumables for the supervised consumption service. Team members had access to the internet and to a range of up-to-date written reference resources available, including the British National Formulary. Computers were password protected and assembled bags were stored within the dispensary and in totes behind the medicine counter, this meant people's details on bag labels were not visible to members of the public.

## 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.	