

Registered pharmacy inspection report

Pharmacy Name: Neil Pharmacy, 95 Wenlock Road, SOUTH SHIELDS,
Tyne and Wear, NE34 9BD

Pharmacy reference: 1077013

Type of pharmacy: Community

Date of inspection: 12/11/2020

Pharmacy context

This community pharmacy is in the suburbs of South Shields. The pharmacy's main activities are dispensing NHS prescriptions, selling over-the-counter medicines and delivering medicines to 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. This 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	Not assessed	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not identify and sufficiently manage the risks with all of its services especially in relation to the sale and supply of codeine linctus to people. This is a medicine that can be misused and some vulnerable people may obtain this medicine and it could cause them harm. The pharmacy has written procedures for team members to follow to help them provide services safely. But there is limited evidence of recent reviews and reading of these. So, team members may not be clear about the safest way to supply medicines. The pharmacy team members respond appropriately when errors happen and make some changes to help prevent similar errors happening again. But they don't record all their errors which means they do not have all the information to help identify patterns and reduce errors. The pharmacy keeps most records as required by law but on occasions these are not completed in a timely manner. People using the pharmacy can raise concerns and provide feedback.

Inspector's evidence

The inspection was undertaken during the COVID-19 pandemic. The pharmacy had identified some changes needed to help manage risks of virus transmission. The pharmacy team members cleaned the pharmacy more frequently and used hand sanitiser, in addition to frequent hand washing. Team members had received individual risk assessments to identify their personal risk. They wore face coverings, but some were not Type IIR face masks. The team members put the recommended ones on during the inspection. The team was aware of current information in relation to the COVID-19 pandemic such as the process for testing, if required, under the government guidelines and discussion took place about wearing the required level of personal protective equipment (PPE). The pharmacy displayed COVID-19 information posters and had a separate poster reminding people using the pharmacy to wear face coverings. The superintendent pharmacist (SI) advised she had a business continuity plan in place and had links with other pharmacies in the area.

The SI advised that she was in the process of reviewing all the standard operating procedures (SOPs) as they were past their review date. She explained she had received new templates to update these. And stated that this was a job for her to do. She produced two large folders with some SOPs and explained that there was another folder which was at home. This folder included the SOPs which referred to over-the-counter sales and products liable to abuse and misuse. The SOPs in the two folders had preparation dates of October 2015 and review dates of September 2017. The SI explained that she had reviewed the SOPs since the first preparation and review dates. Stickers on some SOPs indicated that particular SOPs were no longer applicable. There were a few signatures seen to confirm the team members had read some SOPs, but these were not dated. The SI stated that not much had changed since the last versions of the SOPs and not in relation to medicines liable to abuse and misuse. The inspector subsequently received an email from the SI including the SOPs for sale of OTC medicines. The SOP for the sale of OTC medicines without the intervention of a pharmacist advised that if the team member had any concerns, they should refer to the pharmacist. It stated if there was a pattern of symptoms that they did not feel confident about to refer to the pharmacist. It reminded the team of certain medicines that could be abused. And to 'refer to the pharmacist if the purchaser wanted to buy a lot or had been in several times that day or week to buy'. This named codeine linctus and referred to repeat sales. The SOP said to 'record the item sold and any advice given on a patient's record if they were a regular customer'. There were some signatures from team members dated February 2018 which indicated they had read the SOP. The SI stated in the email that the SOP for the sale of OTC medicines which included the process

for selling, referring and recording sales of products which were liable to abuse will remain the same when the SOPs are renewed. The SI confirmed no records were kept as she was not aware of regular people returning to the pharmacy for sales of items such as codeine linctus.

The SI thought that the pharmacy sold about ten bottles of codeine linctus each month. And had no realisation of the volumes of codeine linctus which the pharmacy had supplied over the last few years. The SI explained that she did not restrict sales of codeine linctus to be pharmacist only sales, with all team members being able to sell it. She thought that she was aware of all sales of codeine linctus, due to where she stood in the dispensary. The team members had not considered the amount of codeine linctus sold.

The pharmacy had a specific template to record near miss errors found and corrected during the dispensing process. But the team members had lapsed in completing these since the end of last year when the pharmacy had undergone a refit. They provided examples where different brands had contributed to picking errors. They discussed errors together and sometimes separated items on the shelves to minimise a similar error occurring. The pharmacy had a procedure for handling complaints, and it had a notice displayed in the pharmacy which explained the complaints process. There was a folder kept with a template which the pharmacist completed if someone notified the pharmacy of an error. Some historic records were in the folder and showed actions taken within the pharmacy for future improvement. The pharmacy gathered feedback through the annual patient satisfaction survey and had received several positive comments. The pharmacy had indemnity insurance with an expiry date of 30 September 2021.

The pharmacy displayed the correct responsible pharmacist (RP) notice. And the pharmacist completed the responsible pharmacist records as required. A sample of controlled drugs (CD) registers looked at found that the pharmacy generally completed stock balance checks every two months. Prior to the start of the pandemic the checks had been undertaken monthly. The last stock check showed September 2020. The SI advised that since the beginning of October she had not entered any prescriptions or invoices for CDs. She showed the inspector a basket which contained all the invoices and prescriptions which she had not entered. There were several prescriptions, with the oldest dated 2 October 2020. And a similar number of invoices. She explained that this month the pharmacy had been short of staff, due to holidays and also the pharmacist who assisted as second cover every fortnight had missed the previous Monday. So, she had let this task slip. After the inspection the SI contacted the inspector to advise that she had completed all the entries. She provided reassurance that she would keep the registers up to date in the future. The pharmacy recorded CDs which people had returned for disposal and records showed the team generally destroyed the CDs on the same day people returned these. The private prescription register had few entries. The pharmacy displayed information on the confidential data kept and how it complied with legislation. It had a folder with information which the SI had updated in January 2020. The pharmacy team members kept people's private information safely and shredded confidential waste. The SI advised that prior to the refit the pharmacy had a company attend onsite to shred obsolete paperwork due to volume required to be securely disposed.

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 learn from the pharmacist and each other to keep their knowledge and skills up to date. Team members know how to raise concerns if they have any.

Inspector's evidence

The SI was present as responsible pharmacist (RP). The SI said that she worked full time and rarely had time off. She advised that usually every second Monday a locum pharmacist came to assist, and sometimes provided additional holiday cover. Also present were a Pre-Reg and a dispenser. A technician and two other dispensers were on days off. The team members had experience, with working at the pharmacy for a number of years, including the Pre-Reg who had worked at the pharmacy since school and while being a student. There was also a pharmacy student who worked mostly on Saturdays who was completing the Medicines Counter Assistants (MCA) course. The team members certificates and qualifications were displayed in the pharmacy. There were two established drivers who worked part time. Another person had started at the beginning of the year and completed induction training and reading of the SOP for delivery. He was also involved in preparation of some Health and Safety documents and supported the pharmacy with other aspects of the business.

The team members reported that they had worked well together during the COVID-19 pandemic. And they had supported each other with the increased workload and uncertainty in ways of working. The pharmacist advised that some local pharmacies had formed a WhatsApp group and kept in contact through this and shared information, particularly in relation to COVID-19.

The SI kept up to date with the PSNC bulletins and information from various websites including the GPhC's notable practice. She advised she had completed her reflective account for her revalidation. The Pre-Reg had one afternoon a week off for study. She also attended virtual study groups with a local university. Due to the pandemic the university had changed the ways of working. The Pre-Reg explained that she received homework to prepare for discussions in groups online. There was a whistleblowing policy and telephone numbers were available so the team members could easily and confidentially raise any concerns outside the pharmacy if needed.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy premises are clean, secure and suitable for the services provided. The pharmacy has good facilities to meet the needs of people requiring privacy when using the pharmacy services. The pharmacy team members take appropriate steps to reduce the risk of COVID-19 infection.

Inspector's evidence

The pharmacy was clean, tidy and hygienic. Since the start of the pandemic it had put a clear plastic screen at the medicines counter, and it had installed a physical barrier at the entrance to the dispensary to stop people approaching this area. The pharmacy allowed two to three people in at any one time. It had moved the chairs in the retail area which allowed people using these to maintain social distancing. The team had increased the frequency of cleaning to help reduce the risk of infection. The public space presented a safe environment. The pharmacy had a refit at the end of 2019. This had provided more space with a room for compliance pack preparation, a dedicated area for the delivery drivers, more storage facilities and new toilet facilities for the team. The sinks, benches, shelves and flooring were all clean. The room temperature was comfortable, and the pharmacy was well lit.

The pharmacy had a reasonable sized, signposted, sound-proofed consultation room. The team used this during the pandemic for some services such as blood pressure monitoring, flu vaccinations and the supervision of methadone service when this resumed. The team members removed unnecessary items to ease cleaning. They wiped down handles and chairs after anyone used the room. The chairs had cloth seats and they covered these with plastic sheeting but after discussion thought it would be better to replace these with plastic, easier to wipe chairs.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy mostly manages and delivers its services safely. But does not have adequate safeguards to properly monitor the safe sale and supply of codeine linctus. The pharmacy obtains its medicines from reputable sources and it generally stores them appropriately. The pharmacy's services are easily accessible to people.

Inspector's evidence

The pharmacy was accessible to all, including patients with mobility difficulties and wheelchairs. There was a small step at the door and the team assisted any person requiring help. Due to social distancing the team had moved the customer seating and cleaned chairs after use. The pharmacy displayed its services in the window which mainly focused on the flu vaccination service and COVID-19 information. The hours of opening were on the door. The pharmacy had a defined professional area. And items for sale were mostly healthcare related. People could not self-select Pharmacy medicines and the team members assisted them with supply of these.

The pharmacy had six 200ml bottles of codeine linctus in stock. Five of the bottles were on a shelf in the retail part of the pharmacy behind the medicines counter and were not price marked. A team member confirmed that the cost was £4.49, and the bottles were not priced as the team members knew how much it cost. And added that some other products the pharmacy did not price mark included pholcodine linctus and paracetamol. The pharmacy had ordered the six bottles the previous night as it had received an NHS prescription and the team had realised there was no stock left. The SI confirmed that she told the dispenser to order six bottles. The invoice from DE Pharmaceuticals confirmed the receipt of bottles of codeine linctus on 12 November 2020. One of the 200ml bottles of codeine linctus was in a basket with a prescription dated 11 November 2020 for an NHS prescription prescribed by a local doctor in South Shields. The label stated a dose of one 5ml spoonful three times a day and was waiting for a check as the final part of the dispensing process. When asked about the number of NHS prescriptions received for codeine linctus the team advised that there were a few. There were no private prescription sales for codeine linctus.

The company owned another pharmacy about two miles away. The SI occasionally worked there on Saturdays and confirmed that pharmacy did not stock codeine linctus and only obtained it for prescriptions. It ordered any codeine linctus directly from its wholesaler if required for a prescription. No stock was transferred from this pharmacy.

The SI confirmed the company stored all the monthly invoices at the company's office. The SI confirmed DE pharmaceuticals, AAH, Alliance and OTC as wholesalers used by the pharmacy, with DE pharmaceuticals for purchases of codeine linctus. The SI could not confirm the amount of codeine linctus purchased. The pharmacy's till did not provide point of sale data, so there was no record of codeine linctus sales. The SI had not known the amounts that had been purchased over the last few years.

When asked about the process for sales for codeine linctus, the team members knew about medicines liable to misuse. They described that some people asked for codeine linctus by name and they would go through the WWHAM (Who, What, How, Action, Medication) questions and try to recommend an alternative. They described how they told people that codeine linctus should only be used for a few

days and then they needed to go to their doctor. If people returned, they would refer them to their doctor. They stated they would definitely only ever sell one bottle of codeine linctus at a time to anyone. This confirmed the process in the SOP. The pre-registration trainee (Pre-Reg) stated she had completed the MCA course which covered medicines liable to abuse. The team explained that they discussed medicines liable to abuse with the pharmacy student as he was completing the MCA course and the topic had come up in the course. The SI described how she recommended different products, such as pholcodine or Robitussin, for a dry persistent cough due to the addictive nature of codeine linctus. If someone asked for codeine linctus by name, the SI would sometimes refer them to their doctor but usually gave them codeine linctus with advice that it may cause drowsiness and not to use it for more than a few days.

The SI recalled that a year or so ago, a person had been asking for codeine linctus regularly. She had spoken with them and had referred them to the Drug and Alcohol unit. The SI remembered that the person had come back weeks later and thanked her for the advice. There was no record made but the dispenser added that the person had been grateful for the support. The SI explained that generally requests for codeine linctus were not from the local people who used the pharmacy regularly. She had not recognised any people returning to buy it, except that during the summer she noticed a few more people asking for codeine linctus and the pharmacy had refused some requests for repeat sales. There were no records for any interventions of requests, refusals or advice given. The SI confirmed at that time she had moved codeine linctus from view as it was then easier to refuse sales. But after the summer codeine linctus had been put back on the shelf in the retail area. Following the inspection, the SI confirmed that she had not realised the volume of codeine linctus which had been sold, in particular high quantities some months. She advised she had removed codeine linctus from sale and would only supply on prescriptions.

The SI mentioned concerns over other codeine-containing products and monitored sales of these due to issues with potential abuse. She said she had never felt the need to keep a record of any person's name regarding these or codeine linctus sales. Some people told her that they had had a consultation with the doctor who had advised them to purchase codeine linctus. The doctors referred them to the pharmacy to purchase codeine linctus as it was cheaper to buy that pay a prescription charge. But the SI had not discussed this with any doctor. The SI felt that she made sales appropriately and usually offered people alternatives. And if supplied she gave advice to use for limited number of days. The pharmacy supplied medicines to people on the Minor Ailments Scheme and the SI said that often people did not want to pay so obtained simple linctus for a cough through the scheme. The pharmacy had between fifty to sixty bottles of simple linctus on open display. It also had several rows with bottles of pholcodine linctus.

Towards the end of the inspection a person came in, who requested a bottle of codeine linctus. The SI attended to the person. The inspector heard that the request was for someone else who would not go to see their doctor. The SI asked questions such as how long the person had had the cough and what type of cough. The SI offered an alternative, the person present advised that the person had used it last November and requested it again. The SI explained it was for short term use, may cause drowsiness and sold a bottle.

The pharmacy workflow provided different sections for dispensing activities with dedicated benches for assembly and checking, with a separate room for compliance pack preparation. The pharmacy team members used baskets to keep prescriptions separate during the dispensing process. Prescriptions for people waiting were marked which helped plan workload. A large proportion of prescriptions were delivered by the pharmacy. The SI advised she phoned people if she required to provide any additional counselling. Or prescriptions were left to one side if the person was coming to the pharmacy and they would be counselled when the medicines were given to them. The labels had 'dispensed by' and

'checked by' boxes but of the checked items observed, only the pharmacist had completed the box for the final check. The team advised they used CD and fridge stickers on bags and prescriptions. This prompted the person handing the medication over in the pharmacy or to the delivery drivers that they needed to add some medication to complete the supply. The pharmacy team members were aware of the valproate Pregnancy Prevention Programme (PPP). They had one person in the at-risk group who had been counselled. The pharmacy had information to hand out to support counselling.

The pharmacy's service had been limited during the pandemic, but some had continued such as the Minor Ailments scheme and the local GP to Pharmacy scheme. Both these services were popular with upwards of ten requests daily for minor ailments and sometimes three each day for the 'GP to Pharmacy' scheme. The GP to Pharmacy scheme linked to the surgery's computer system and the pharmacy followed Patient Group Directions (PGDs) for treatments for conditions such as impetigo and urinary tract infections. The pharmacy received requests for blood pressure checks through the scheme and continued to provide these. It provided a smoking cessation service, but this no longer included taking carbon monoxide readings. Some smoking cessation consultations were undertaken remotely. People requesting Emergency Hormonal Contraception (EHC) generally had a conversation in the pharmacy with privacy maintained. The pharmacy had completed several flu vaccinations with most being undertaken, without an appointment, as walk-ins. The Pre-Reg generally took the required information from people and recorded this on PharmOutcomes and the pharmacist gave the vaccination. The pharmacy provided the Community Pharmacist Consultation Service (CPCS). People accessed the CPCS service through NHS 111 referrals. These requests generally occurred on a Saturday.

The pharmacy supplied medicines to around 100 people in multi-compartment compliance packs to help them take their medicines. The pharmacy reviewed the process following moving the dispensing and management of the service to the dedicated room after the refit. It had records in files for people and recorded any changes on their records. It kept a book for any telephone conversations to ensure actions were undertaken. The pharmacy prepared four week's medication together and most people received one week's supply at a time, with the Patient information leaflets (PILs) supplied once with each cycle. The pharmacy provided a substance misuse service to around 12 people. At the start of the COVID-19 pandemic, people had received their medication weekly but now about half of the people received daily supervised supplies and other weekly supplies, supervised on the day of collection. About 80 per cent of prescriptions were usually delivered by the pharmacy and this had slightly increased during the pandemic. The pharmacy reviewed its delivery process during the pandemic and signatures from the person receiving the medication had stopped. The drivers kept a record of when they delivered.

The pharmacy generally stored medicines in an organised way, but it had several loose foil strips and some medicines transferred from original manufacturer's containers into incompletely labelled bottles on the dispensary shelves. The SI explained that if the team received a prescription with the quantity, 28 tablets, and the original box contained 56, the team would give the person the original box and place the loose strips onto the shelf. She confirmed this was a bad habit which she needed to review. She recognised the information required on any inadequately labelled bottles. The pharmacy had a refrigerator from a recognised supplier. This was appropriate for the volume of medicines requiring storage at such temperatures. The team members recorded temperature readings daily on the computer and they checked these to ensure the refrigerator remained within the required temperature range.

The pharmacy team generally checked expiry dates on products on a three-month cycle and had completed the last cycle in the summer. The team members marked short-dated items and they took these off the shelf prior to the expiry date. The team members marked liquid medication with the date of opening which allowed them to check to ensure the liquid was still suitable for use. The team used

appropriate medicinal waste bins for patient returned medication. The contents of the bins were securely disposed of via the waste management contractor. The pharmacy had appropriate denaturing kits for the destruction of CDs. The pharmacy had a process to receive drug safety alerts and recalls from the Medicines and Healthcare products Regulatory Agency (MHRA). The team actioned these and kept records of the action taken.

Principle 5 - Equipment and facilities ✓ Not assessed

Summary findings

Equipment and facilities were not inspected on this occasion.

Inspector's evidence

Equipment and facilities were not inspected on this occasion.

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.