

Registered pharmacy inspection report

Pharmacy Name: Stevenson; F.F. & R., 389a James Reckitt Avenue,
HULL, North Humberside, HU8 0JE

Pharmacy reference: 1032099

Type of pharmacy: Community

Date of inspection: 23/09/2020

Pharmacy context

This is a small independent pharmacy providing services to the local community. The pharmacy's main activities are dispensing NHS prescriptions and selling over-the-counter medicines. 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. This inspection took place during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 in buying and selling 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. This means some vulnerable people may obtain medicines that could cause them harm. The pharmacy keeps the records it must by law. But it doesn't complete checks or keep other records as is best practice. So, there is a risk the pharmacy team may not detect mistakes. The team knows how to help protect the welfare of vulnerable people. And people using the pharmacy can raise concerns and provide feedback.

Inspector's evidence

The pharmacy was inspected during the COVID-19 pandemic and it had identified some changes needed to help manage the risks of virus transmission. The pharmacy had a clear plastic screen in place at the medicines counter. The pharmacy had cleaning sprays behind the counter. The pharmacy team members cleaned regularly. They frequently washed their hands and sanitised their hands between people they served at the counter. The pharmacy had a display unit with hand sanitiser, face masks and thermometers for people to buy. The pharmacist advised that prior to the lockdown due to the pandemic he had monitored the team members temperatures daily. The team had discussed the implications of COVID-19 and felt supported by the pharmacist. The pharmacist had not undertaken written individual risk assessments for the team members but advised he knew them well and they had fully discussed their concerns and needs. The pharmacist was aware of the requirements for reporting cases of COVID-19. The pharmacy team were not wearing face masks but put these on during the inspection.

The pharmacy had a range of standard operating procedures (SOPs) for various key processes. These had a review date of July 2018. The SOPs had signature sheets but none of the current pharmacy team members had signed these. The majority of the SOPs were original versions dating back several years. The pharmacist advised when he reviewed these, he placed a signed dispensing label with the next date of review. Very few of the SOPs had any changes made to them over the years and some showed incorrect details of team members who had left the pharmacy many years previously. One of the medicines counter assistants (MCA) advised she had read all of the SOPs but not signed them after reading. Another MCA was not certain if she had read all the ones relevant to her role and confirmed she had not signed any. The new starter had not read any of the SOPs.

The pharmacy displayed the SOP which related to sales of pharmacy-controlled medicines under the till. It referred to WWHAM questions for selling over-the-counter (OTC) medicines. It had a label attached to it with a review date of July 2018 which the pharmacist had signed. The pharmacist advised that the names of MCAs listed on that SOP were out of date as none of them worked at the pharmacy anymore. The SOP did not specifically cover sales of codeine linctus but provided instructions about taking additional care with sales to persons under the age of 16 years, for laxatives and products containing ephedrine and pseudoephedrine. The MCA explained the questions she asked, and she consulted the pharmacist if required before she made any sales, following the SOP. The SOP stated to follow the training provided in the MCA course and to consult the pharmacist if there were any doubts regarding the sale. The MCA advised that she did not recommend codeine linctus for dry coughs and referred to

other products available. The pharmacist confirmed that he made repeated sales of codeine linctus to a few people visiting the pharmacy regularly. He said he was aware that people could become addicted to it. He advised he had no real problems selling it, due to its historical use and he always spoke to the people. He felt it was not doing any harm. He regularly sold more than one bottle in a single transaction. The pharmacy only received a few NHS prescriptions for codeine linctus with perhaps a 200ml bottle of codeine linctus being dispensed once every three months.

The pharmacist explained that he had a process for recording near miss errors found and corrected during the dispensing process. He advised that he acted following any near miss errors made but advised there were few so had no records to show. He provided examples of selection errors. One included a picking error with Premarin and Prempack C and he had placed a warning sticker on the shelf as a reminder for future selections. Another was the incorrect strength of warfarin and he had placed the boxes with the full side of the box showing and spaced these out on a separate shelf. He advised he had done this as a patient safety measure. The pharmacy had information displayed in the pharmacy which explained the complaints process. It gathered feedback through the annual patient satisfaction survey. It had received several positive comments on the last survey which it displayed in the window. Comments included friendly, helpful and willing to oblige. The pharmacy had survey forms on the counter for people to take but advised due to the current pandemic people were not willing to complete these. The pharmacy had indemnity insurance with an expiry date of 31 December 2020.

The pharmacy displayed the correct responsible pharmacist notice. And the pharmacist completed the responsible pharmacist records. The controlled drugs (CD) registers generally complied with the legal requirements. The pharmacist advised he usually checked the running balances at the time of dispensing, but he did not undertake regular stock audits. The pharmacy did not maintain a record of CDs which people had returned for disposal. The CD patient-returned items were in a clear bag on a separate shelf in the CD cabinet. This was accessible by the pharmacist only. A discussion took place regarding the best practice to keep a record of returned CDs for destruction and to complete regular stock audits to suitably manage risks.

The pharmacy had a private prescription register but there were no recent entries. The pharmacist advised that he had not seen a private prescription for years. There were no special records for unlicensed products as it was explained that the local policy in this area was not to prescribe any unlicensed medicines. The pharmacy displayed information on the confidential data it kept and how it looked after this information. The pharmacy team kept people's private information safely. They stored confidential waste in separate containers for shredding. The pharmacy had information relating to safeguarding vulnerable adults and children. The pharmacist was aware how to access local safeguarding contact details.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy team members have the necessary qualifications for the roles they do. Newer team members are in the process of registering on a recognised course as required. The pharmacist adequately manages the dispensing workload alone, as other team members do not have the qualification training to help. So, they may miss opportunities to fully support each other and develop in their roles. They complete some ongoing training on an adhoc basis.

Inspector's evidence

There was one pharmacist and three team members who worked in the pharmacy. At the time of the inspection they were all present. Two of them were qualified MCAs. One worked 38 hours a week and had worked at the pharmacy for about six years. The other worked 16 hours a week and had worked about three years in the pharmacy. The pharmacist worked six days a week and had done so for the last four to five years. He advised that during the pandemic he often worked 12 hours a day to keep the backlog down. He had a list of locums should he require cover for the pharmacy.

The MCA working the most hours had also completed an additional training module which allowed her to assist with stock management tasks in the dispensary. The pharmacist advised that she did not undertake any dispensing but supported him in the dispensary. She did not dispense or label. Her roles included bagging of items once the pharmacist had checked them. The pharmacist explained that he talked through the prescription and items, with her, as part of his accuracy check. The pharmacy was very quiet during the inspection. The pharmacist dispensed a couple of prescriptions while people waited, and a few completed bagged medicines were handed out to people. The MCA was not involved in the dispensing of these medicines. She checked the computer system to see if an electronic prescription had uploaded from the NHS system for dispensing. Due to the checking process described it was discussed whether it would be beneficial and appropriate for the MCA to undertake a dispensing course. The MCA advised she would complete a course if required to do so. The third team member had started working in the pharmacy two weeks earlier and had been employed to work 30 hours a week. She had not commenced formal training but would commence required training within the guidelines. She was being supported by the other MCA who was working at the counter with her.

The pharmacist advised that he shared information with the team during informal conversations. The pharmacy received materials from one of the main suppliers, Alliance. The pharmacist shared trade magazines and articles with the team. The pharmacist advised he maintained his continuing professional development and was in the process of completing his revalidation. He was aware of the changes to the process this year and that he required to submit a reflective account only. The pharmacist advised that he kept up to date using the internet as his main resource for information. He advised that he previously attended local courses which the then local Primary Care Trust (PCT) had organised. Since these had stopped, several years ago, there had been few courses in the area. The inspector directed to the GPhC and Pharmaceutical Services Negotiating Committee (PSNC) for further information, particularly in relation to COVID-19 pandemic.

The pharmacist infrequently used sites such as the GPhC or PSNC for up-to-date information. He had not participated in the latest Pharmacy Quality Scheme (PQS) which supported contractors to additionally comply with elements of Health and Safety legislation during the COVID-19 pandemic. He

felt it was not worth doing for the payment. The pharmacy team had not undertaken training on health campaigns such as sepsis or safeguarding.

The pharmacy displayed the SOP with the sale of medicines protocol behind the medicines counter. This included the WWHAM questioning. The MCA explained the process for OTC sales recommendations. She advised that she referred to the pharmacist when necessary. The team advised that they had worked well together during the pandemic and felt supported by the pharmacist.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is clean, secure and suitably maintained to the standards required. The pharmacy team have access to adequate facilities which allows people to have a conversation in private.

Inspector's evidence

The pharmacy was clean, tidy and hygienic. It only allowed two people into the pharmacy at any one time to maintain social distancing. The pharmacy team members had increased the frequency of cleaning to help reduce the risk of infection. They had a range of cleaning products behind the counter which they used frequently during the inspection. The dispensary was fitted out to an acceptable standard with adequate space for dispensing, storing stock and medicines and devices waiting for collection. The pharmacist kept the main dispensing bench clear for dispensing and the other bench was full of completed, bagged prescriptions for hand out. These were layout in an organised manner with prescriptions attached. A few larger bags were on the floor. The sinks, benches, shelves and flooring were all clean and the team cleaned as required.

The pharmacy team kept the floor spaces clear to reduce the risk of trip hazards. The room temperature was comfortable, and the pharmacy was well lit. The pharmacy did not have a consultation room, but the team had access to a room at the rear of the dispensary. The team members used this if people wanted to speak with a member of its team in private. The pharmacist advised that a member of the team escorted people through to the room and the pharmacy stored no person identifiable information at this side of the dispensary that people walked passed. The room did not form part of the registered pharmacy premises. It was neat and tidy, and the pharmacist used this as an office. It provided suitable privacy. No other registerable activities took place in this room. During the pandemic, due to the reduced number of people accessing the pharmacy at one time it was possible to have some private conversations in the retail area. There was a cat present in the rear room and it generally stayed in this room but could access the dispensary as the door between the rooms were kept open. Advice was given to keep the door shut and consider using the small hallway for any private discussions.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy provides some services in a way that puts people's safety at risk. It does not have adequate safeguards in place to manage the safe sale and supply of codeine linctus. And it does not appropriately monitor and control the sales of codeine linctus. The pharmacy gets its medicines from reputable sources and it stores them appropriately. It does not always maintain suitable records to manage its services and medicines effectively.

Inspector's evidence

The pharmacy had a push/pull door with a small step from the street level. A clearly sign-posted doorbell was in place for people to use to alert the pharmacy team if they required assistance into the pharmacy. There was a chair available for people to use and the team members cleaned this after use. The pharmacy had a range of leaflets available for people, including a practice leaflet. A notice on the door displayed the change in hours of opening as the pharmacy closed for an additional half hour at lunchtime since the start of the pandemic. The pharmacist advised that he had continued to close for the additional half hour each day and said he had checked that this was permitted. The pharmacist explained this was when he undertook any required deliveries. He advised that since the start of the pandemic there had been a slight increase in requests for deliveries which he had managed. He did not keep any record of deliveries but knew who he delivered to. He had reviewed his process during the pandemic and left medicines at the doorstep, stood away and waited for people to pick up their medicines. The pharmacy had a defined professional area. And items for sale were mostly healthcare related. The pharmacy kept pharmacy medicines either behind the counter or in a unit with glass-fronted sliding doors within the retail area. The MCA advised that people did not to self-select medicines from behind the glass doors. She assisted people who wanted any of these items. Medicines kept behind the glass doors included a range of pharmacy medicines for cough treatments and pain relief, including codeine linctus. The MCA advised that she asked the pharmacist if there were any doubts regarding any sale. She advised that there were a few people who regularly purchased codeine linctus and the pharmacist was involved in these sales. She explained some questions she asked before making OTC sales and she consulted the pharmacist if required. She advised she normally recommended brands of coughs medicines if someone wanted something for a dry cough. She advised of the WWHAM questions for selling OTC medicines and referred to the notice (SOP) displayed under the till which related to sales of pharmacy-controlled medicines.

The pharmacist agreed sales of codeine linctus were referred to him and that he only sold codeine linctus regularly to a limited number of people. He advised that he had made sales of codeine linctus to these people weekly or more than once a week. And that he sold more than one 200ml bottle at a time. They had told him it was for their own use. The pharmacist thought they were probably addicted to it. He confirmed he had advised them to see their doctors but had no records of any conversations. He had never spoken to any doctors about codeine linctus. He explained he continued to sell to them as he felt it was not doing any harm and that he did not give any further advice as he felt they would not take the advice. The pharmacist confirmed he had no real problems selling it and referred to its use historically. He confirmed he had probably been supplying it to them for about four years. He advised he had never offered them any alternative for codeine linctus. The MCAs agreed with the pharmacist's comments. The pharmacist advised he would stop selling codeine linctus if asked to do so.

The pharmacist prepared the labels for prescriptions. Then he moved these to a clear bench and dispensed the items. He advised he talked through the names of the items on the prescription with the MCA who was in the dispensary with him. He checked and she bagged the items. This formed part of his accuracy check. If any prescriptions had a fridge item, he put the completed bag with all their medicines into the fridge until collection. And the same for any prescriptions containing any CDs. The completed bag with items was stored in the CD cabinet. The pharmacy had some processes in place to identify people taking high-risk medicines. The pharmacist discussed the valproate Pregnancy Prevention Programme (PPP). The pharmacy had some people taking valproate but no one in the 'at-risk' group. The pharmacy had information to hand out if any person who met the criteria presented a prescription. The pharmacy kept original prescriptions for medicines with any items owing to people on a clip and completed these when the medicines became available. The pharmacist advised that they usually managed to obtain items for people and only had a few owings at any time.

The pharmacy supplied medicines to around five people in multi-compartment compliance packs to help them take their medicines. It had a dedicated area where it kept the materials and information for the compliance packs. The pharmacist advised that there had not been any changes in medication for these people. They were all stable, but he preferred to dispense weekly. The pharmacy supplied the compliance packs weekly to people and patient information leaflets (PILs) once every four weeks.

The pharmacy obtained medicines from recognised wholesales, AAH, Alliance and DE pharmaceuticals. But it didn't keep the invoices. It stored medicines in an organised way, within the original manufacturers packaging and at an appropriate temperature. The MCA in the dispensary advised she checked the stock for expiry dates as part of her stock management duties. She routinely checked but kept no records. No out-of-date items were on the general dispensing shelves. The pharmacy had a small number of liquid medicines. The pharmacist advised he did not keep split bottles of liquids and there were no split bottles seen on the shelves. The pharmacy had a refrigerator from a recognised supplier. This was appropriate for the volume of medicines requiring storage at such temperatures. The pharmacy had been part of a project group when the Falsified Medicines Directive (FMD) commenced. This had not progressed, and the pharmacy had not implemented any systems for FMD.

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 CD cabinet looked orderly but some of the current stock was mixed with out-of-date stock which resulted in confusion and increased risk of selecting a medicine that was out of date. The stock levels were low as the pharmacist advised he generally only ordered when he received a prescription. The pharmacy had appropriate denaturing kits for the destruction of CDs, but the pharmacist had not destroyed patient returned medicines for a long time with a bag of medicines waiting destruction. And the pharmacy had out-of-date CD stock dating back to 2007. No arrangements were in place for authorised destruction of these. The pharmacy had a process to receive drug safety alerts and recalls from the Medicines and Healthcare products Regulatory Agency (MHRA). The pharmacist actioned these but kept no records of the action taken.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for providing its service. It demonstrates how it uses these to maintain people's confidentiality.

Inspector's evidence

The pharmacy had access to a range of up-to-date reference sources, including the British National Formulary (BNF). And used the internet as an additional resource for up-to-date information. The dispensary computer was password protected and out of view of the public. The pharmacy had measuring equipment available of a suitable standard including clean, crown-stamped measures. It also had a range of equipment for counting loose tablets and capsules. It had resources and facilities in place, such as hand sanitiser, to manage infection control.

The pharmacy stored completed prescriptions in the dispensary away from public view. It held other private information in the dispensary. The team used cordless phones for private conversations.

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.