

Registered pharmacy inspection report

Pharmacy Name: Steve's Chemist, 36 Bridge Road, GRAYS, Essex,
RM17 6BU

Pharmacy reference: 1031172

Type of pharmacy: Community

Date of inspection: 13/11/2020

Pharmacy context

The pharmacy is located in a small parade of shops in a residential area. As well as dispensing NHS prescriptions the pharmacy supplies medicines in multi-compartment compliance packs to some people who need help managing their medicines. This was a targeted inspection as intelligence had been received that the pharmacy had been obtaining unusually large quantities of codeine linctus which is addictive and can be abused. The inspection was undertaken during the Covid-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Improvement Action Plan; 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 adequately identify or manage the risks associated with selling codeine linctus over the counter. It has been purchasing and selling large amounts of codeine linctus. The pharmacy does not have the appropriate governance in place to manage this situation. And there are no documented details about the action it has taken to ensure medicines which are addictive, can be abused and misused are sold safely. This means people's health is at risk.
		1.2	Standard not met	The pharmacy is not selling codeine linctus safely. It does not have any systems in place or audit trails to identify, monitor and review sales of this medicine.
		1.6	Standard not met	The pharmacy does not keep all its records fully in line with legal requirements.
		1.7	Standard not met	The pharmacy does not always manage confidential information properly or securely dispose of confidential waste. This could result in people's personal information being disclosed.
2. Staff	Standards not all met	2.2	Standard not met	Not all team members do the relevant accredited training for the tasks that they carry out.
3. Premises	Standards not all met	3.1	Standard not met	There are significant tripping hazards in the dispensary which presents a risk to staff.
		3.3	Standard not met	The premises are not maintained to an appropriate level of hygiene for some of the services provided.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy is purchasing and selling excessive amounts of codeine linctus without the appropriate safeguards in place to prevent its misuse and abuse.
		4.3	Standard not met	The pharmacy does not always store patient-returned medicines separately from its current stock medicines. Not all its stock medicines are packaged or labelled appropriately. And it does not always appropriately restrict access to some

Principle	Principle finding	Exception standard reference	Notable practice	Why
				medicines which require additional security measures.
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 have the appropriate safeguards in place to identify, monitor and manage all the risks associated with selling codeine linctus. It is buying and selling large amounts of codeine linctus, and this could be abused and cause harm. This risks people's safety. The pharmacy's records that it must keep by law are not all complete or accurate. The pharmacy doesn't protect people's private information properly. The pharmacy's practices relating to its other services are generally safe. This includes managing the risks associated with COVID-19.

Inspector's evidence

Standard operating procedures (SOPs) were available and team members had read and signed SOPs which were relevant to their roles. Team roles were defined within the SOPs. The superintendent pharmacist (SI) had recently implemented new SOPs using the Avicenna templates. There was an SOP for selling over-the-counter (OTC) medicines. However, this only briefly mentioned referring to the responsible pharmacist (RP) before selling medicines that could be misused such as those containing codeine or pseudoephedrine. There was no further documented policy or specific information on how to manage excessive requests or the risks of selling these medicines.

The pharmacy's team members, including the RP, were aware that OTC codeine-containing medicines were addictive. The RP, who was also one of the owners explained that the pharmacy had not dispensed any NHS or private prescriptions for codeine linctus. He confirmed the team had been selling codeine linctus over the counter. The RP said that team members checked symptoms, tried recommending other products and used an established sales-of-medicines protocol (WWHAM) before selling codeine linctus. He said that people were requesting this for a dry cough and had been recommended the product by their friends or family. If the RP noticed the same person making multiple requests, the sale was refused. The dispenser said that she very rarely worked on the medicines counter and would not sell codeine linctus. She had noticed that there had been a few calls from people asking if the pharmacy stocked codeine linctus. The team did not document any details of refusals. This limited the ability of the pharmacy to demonstrate that its team members had been taking appropriate steps to prevent misuse from happening. There had been no details documented of any interventions made with OTC sales of codeine linctus and there were no written records of the sales. The RP could not say exactly how many requests for codeine linctus were seen in a day, week or month. The pharmacy used an old-fashioned cash register where prices of medicines were manually entered before selling the product to people. This meant that the pharmacy could not identify, monitor or break down the sales of codeine linctus compared to the sales of other medicines over any period. Consequently, this meant that there was no or very limited oversight of the requests and sales of this medicine. At the end of the inspection, the RP informed the inspector that he would stop selling codeine linctus.

The pharmacy had systems in place to identify and manage the risks associated with some of its other services. The team had been routinely ensuring infection control measures were in place. Team members had been provided with personal protective equipment (PPE). The RP explained that the necessary risk assessments to help manage Covid-19 had been completed and this included occupational ones for the staff. Information was displayed at the entrance asking people to wear a mask upon entering and that only two people at a time could enter the premises.

The pharmacy recorded dispensing mistakes which were identified before the medicine was handed out

(near misses) and those where the medicine was handed to a person (dispensing errors). Near misses were recorded on a log as they occurred. Completed near miss record sheets were seen during the inspection. The RP reviewed these at the end of each month and changes were made to ensure mistakes did not reoccur. Following a review Zapain capsules and tablets had been separated on the shelves as had paroxetine and pantoprazole. In the event that a dispensing error occurred this would be recorded online and discussed with the team. The RP said that he had not personally had to deal with a dispensing error.

The correct RP notice was displayed. But the locum pharmacist's notice was also initially displayed and this was removed during the course of the inspection. The team members were aware of the tasks that could and could not be carried out in the absence of the RP. The pharmacy had current professional indemnity insurance. The pharmacy had a complaint procedure. And it completed an annual patient satisfaction survey. As a result of feedback, the team tried to answer the telephone after two to three rings, had improved stock levels to avoid owings and had improved the repeat prescription service.

Records for unlicensed medicines dispensed were well maintained. Private prescription records did not have the accurate date for when the prescription had been issued or the correct prescriber details. Emergency supply records did not always have the nature of the emergency recorded. Controlled drug (CD) registers were generally up to date, but there were a number of incomplete headers seen in a number of registers. CD balance checks were carried out. A random check of a CD medicine complied with the balance recorded in the register. CDs that people had returned were recorded in a register as they were received.

A private prescription was found in the pharmacy, but the prescriber's signature did not appear to be signed in ink. The RP gave an assurance that in future he would ensure thorough checks were carried out before prescriptions were dispensed.

RP records were incomplete; the regular pharmacist who worked at the pharmacy three days a week had never made an entry. And this could mean that the pharmacy would be unable to show who had been the RP on a particular day.

Not all confidential information was held securely, and some was stored where it was visible to people using the pharmacy. The RP had a smartcard to access the NHS electronic systems. An information governance policy was in place which had been discussed with team members. Confidential waste with people's private information on was segregated in a separate bin, and this was usually shredded at the weekend. However, confidential waste was found in the general waste bin. The pharmacy's computers were password protected and screens faced away from people using the pharmacy.

Assembled medicines which were due to be collected by the delivery driver were stored in a tote on the shop floor. These had people's private information clearly visible. These were moved by the RP after it was brought to his attention.

The RP and locum pharmacist had completed the level 2 safeguarding training course. One of the dispensers had completed training with the previous owners and the other dispenser had completed training as part of his previous role. Details of local safeguarding contacts were available.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy has enough staff to manage its workload appropriately but some members of the team are doing tasks that they aren't trained for or qualified in. Staff are given some ongoing training. But this is not very structured, and they are not given time set aside for training. This could make it harder for them to keep their knowledge and skills up to date.

Inspector's evidence

On the day of the inspection the pharmacy team comprised of the RP (one of the owners), a trained dispenser and another team member who the RP said was on trial and had worked at the pharmacy for five days over two weeks. The badge worn by this team member said that he was a 'community volunteer.' The team member was seen to be putting dispensary stock away at the start of the inspection. The trained dispenser worked part time and left part way through the inspection as did the other team member.

One of the other owners also worked full time as a dispenser at the pharmacy but was delayed coming in on the day of the inspection. His wife also worked at the pharmacy doing clerical work. Another owner also worked part time at the pharmacy. Neither of the owners had completed or been enrolled on any formal accredited training despite having worked at the pharmacy since it had been taken over in 2016. The trained dispenser managed the multi-compartment compliance pack service.

The team's performance was informally monitored, and informal, ad-hoc meetings and discussions were held when required. The RP had a chat annually with team members to discuss performance and pay related matters. There were no targets in place.

The trained dispenser asked relevant questions before selling OTC medicines, asked about other medical conditions, symptoms, intended use and knew when to refer to the RP if she was unsure or if excessive requests were seen. When questioned, she explained which medicines she would not sell more than one pack of.

There was no structured ongoing training in place for team members. The RP said that literature was available but team members were not given set-aside time to complete any additional training. The RP described updating team members on changes to guidance or legislation. The dispenser had picked up the change in guidance for dispensing sodium valproate from the prompts on the system.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy does not keep its premises clean. And some areas of the pharmacy including the dispensary are untidy and require maintenance. There are tripping hazards in the dispensary and this presents risks for the staff. The premises are kept secure.

Inspector's evidence

The pharmacy had not been refitted for many years and was dirty in places including the dispensary workbenches. The dispensary and the back area of the premises were cluttered and there was limited space available. Workspace was also limited in the dispensary with little free space available for dispensing and checking. Multi-compartment compliance packs were prepared in a room adjacent to the dispensary. A sink was available for the preparation of medicines but this was being used to store medicines. There was dust and dirt on the shelves and dispensary floor including unidentified loose tablets. Cobwebs were also seen in the dispensary and in the consultation room. The floor in the dispensary was uneven and presented a trip hazard, and the RP explained that the floor had given way and an agreement had been reached with the landlord to have this fixed. The pharmacy was looking to relocate to a larger premises. Team members were observed to use face masks and only two people were being allowed into the pharmacy at any given time. Screens had also been fitted at the counter. The retail area of the pharmacy was large and people waiting were able to maintain distance from other people. Hand sanitiser was also available for team members to use.

The pharmacy had a cellar which the RP said was used to store excess medicines and paperwork. The cellar was accessed via a trap door in the side room which was used to prepare compliance aids. Furniture needed to be moved and the room partly emptied to access the cellar. The cellar did not have any lighting and was damp and dirty. The ceiling had come away on one side which the RP said was the area where the dispensary floor had been damaged. The RP was shocked and surprised by the state of the cellar and said that he did not usually go down. There were no medicines found in the cellar. The RP agreed to ensure no medication was stored there in the future.

The room used for the preparation of multi-compartment compliance packs was also used as the consultation room. The room was accessed from behind the medicines counter. Assembled prescriptions were stored in this room and people's personal information was clearly visible. As the pharmacy did not provide any services, the RP said that the room would no longer be used for consultations and private conversations would be held in a quiet area.

The premises were kept secure from unauthorised access. The room temperature was adequate for the provision of pharmacy services and the safe storage of medicines. The RP said that the pharmacy never became too hot.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy does not provide all of its services safely. It has limited systems to ensure supplies or sales of higher-risk medicines are made safely. It is unable to satisfactorily justify the large quantities of codeine linctus and other medicines liable to abuse that it orders and supplies. And it is not doing enough to satisfy itself that people are not at risk of becoming addicted. The pharmacy obtains its medicines from reputable sources. But it does not store or manage all of its medicines appropriately. The pharmacy provides most of its other services in an appropriate way.

Inspector's evidence

The range of services offered by the pharmacy was adequately promoted. Access into the premises was via two steps from the street, there was a handle to use if people needed it and team members would go and help people who required assistance. Aisles were also wide and clear with easy access to the counter. The local population predominantly were English speaking and the pharmacy had not had issues with languages in the past. Team members were aware that signposting may be necessary where people required an additional or alternative service. The pharmacy had the ability to produce large print labels when needed.

Prescriptions were received electronically, then printed out and labels were processed and placed in a basket. These were dispensed by a dispenser and left for the RP to check. On some occasions when the RP was working on his own, he self-checked. Taking a mental break in between dispensing and checking the prescription was discussed with the RP. Dispensed and checked-by boxes were available but these were only being used by the checker. This would make it difficult to identify who had been involved in the dispensing process if there was an error. Baskets were used to separate prescriptions, preventing transfer of items between people.

The pharmacy supplied medicines to a private practice. The RP gave an assurance of checking with the MHRA if this could be done without a wholesale dealers license (WDL).

The RP had to be prompted and reminded of the change in guidance for dispensing sodium valproate. He said that the computer system automatically printed warning stickers when sodium valproate was dispensed. The RP thought that the SI had completed an audit on the use of sodium valproate.

The RP ran anticoagulant clinics for another pharmacy group when he was not working at the pharmacy. Checks were carried out when people presented to collect prescriptions for warfarin and methotrexate from the pharmacy being inspected but no records were kept.

Some people's medicines were supplied inside multi-compartment compliance packs. The service was managed by the trained dispenser. The pharmacy ordered prescriptions on behalf of people for this service and specific records were kept for this purpose. Any queries were checked with the prescriber and the records were updated accordingly. Descriptions of the medicines inside the packs were provided and patient information leaflets (PILs) were supplied monthly. The pharmacy's driver delivered people's medicines to them and the team kept records about this service. Contactless deliveries were being made due to the Covid-19 pandemic. Failed deliveries were brought back to the pharmacy.

The pharmacy used licensed wholesalers such as AAH, Alliance Healthcare, Sigma, B&S Colorama, DE South, Chemilines and Bestway to obtain medicines and medical devices. The team date-checked medicines for expiry regularly and kept records of when this had happened. However, these records were not available to inspect as the RP said they had been taken home by the SI. Short-dated medicines were identified. There were no date-expired medicines found on the shelves checked. A number of medicines were seen to be stored on the shelves outside of their original packaging. Some medicines were also seen to be stored in brown bottles which did not have any indication of batch number or expiry dates. Medicines were also found to be stored in mixed batches. Some laxatives in bulk packaging which are classified as 'pharmacy only' medicines were seen to be stored on shelves which could be reached by people.

Records examined showed that the pharmacy was ordering large quantities of codeine linctus. When the figures were put to the RP and the SI, both said that they had not realised these quantities were being purchased or sold from the pharmacy.

Fridge temperatures were checked daily and recorded. These were observed to be within the required range for the storage of medicines. Out-of-date and other waste medicines were disposed of in the appropriate containers which were kept separate from stock and collected by a licensed waste carrier. However, a liquid preparation which had part of another pharmacy's dispensing label was found in the dispensary amongst other stock medicines and multi-compartment compliance packs labelled for a person at another pharmacy were also found in the storeroom. The RP was unsure of how these had got there and said that the medicines would not be used and disposed of these during the inspection. CDs were largely held securely, but access to them was not always appropriately restricted.

Drug recalls were received via email and these could be accessed by all team members. Alerts were actioned and stored in a sub-folder. The RP said the pharmacy had signed up with their provider for the Falsified Medicines Directive. However, this had not been activated at the time of the inspection.

Pharmacy stock was manually ordered by all team members. This included codeine linctus. Invoices detailing the purchase of codeine linctus were forwarded to the inspector and those that were present on the premises were obtained. The pharmacy did not have an online presence. The RP also confirmed the pharmacy was not supplying any other organisation or pharmacy with this medicine. The pharmacy did not have a wholesale distribution authorisation (WDA).

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for the services it provides. It generally maintains them properly. But it could do more to ensure that measuring and counting equipment is kept clean at all times.

Inspector's evidence

The pharmacy had a range of glass calibrated measures available. Two of the three measures were unclean, the RP said that these were not used. Tablet counting trays and an electronic tablet counter were also available. There was a thick film of tablet dust in the machine; the RP described that the machine had not been calibrated since the pharmacy had been taken over and said he sometimes double-checked the quantity if it looked incorrect. Speaking to the manufacturer about calibration requirements was discussed. Up-to-date reference sources were available including access to the internet. The pharmacy had a fridge of adequate size.

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.