

# Registered pharmacy inspection report

**Pharmacy Name:** Olive Tree Pharmacy, 463 Stratford Road, Sparkhill,  
BIRMINGHAM, West Midlands, B11 4LD

**Pharmacy reference:** 1091775

**Type of pharmacy:** Community

**Date of inspection:** 10/11/2020

## Pharmacy context

The pharmacy is located on a busy road in Sparkhill, Birmingham. It is open extended hours, seven days a week. It dispenses NHS prescriptions, sells a small range of over-the-counter medicines and provides advice to people about minor ailments. And it has a small number of people who receive instalment supplies for substance misuse treatment. This was an intelligence led inspection undertaken during the Covid-19 pandemic based on information received by the GPhC that the pharmacy had been obtaining unusually large quantities of codeine linctus, which is liable to abuse and misuse. All aspects of the pharmacy were not inspected on this occasion.

## 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
<b>1. Governance</b>	Standards not all met	1.1	Standard not met	The pharmacy does not adequately manage the risks and governance around the purchasing, sale and supply of medicines liable to misuse such as codeine linctus.
		1.1	Standard not met	The pharmacy does not adequately manage the risks and governance around the purchasing, sale and supply of Phenergan elixir.
		1.2	Standard not met	The pharmacy does not audit or monitor its purchases, sales and supplies of medicines liable to misuse such as codeine linctus, so it is unable to identify potential abuse and misuse.
		1.2	Standard not met	The pharmacy does not audit or monitor its purchases, sales and supplies of Phenergan elixir to help identify potential abuse and misuse.
		1.6	Standard not met	The pharmacy does not have adequate systems in place to make sure its records about controlled drugs are always kept in line with statutory requirements.
<b>2. Staff</b>	Standards met	N/A	N/A	N/A
<b>3. Premises</b>	Standards met	N/A	N/A	N/A
<b>4. Services, including medicines management</b>	Standards not all met	4.2	Standard not met	The pharmacy buys and sells large amounts of some medicines which may be liable to misuse or abuse such as codeine linctus without making appropriate checks.
		4.2	Standard not met	The pharmacy buys and sells large amounts of Phenergan elixir without making appropriate checks to safeguard against misuse or abuse.
		4.3	Standard not met	The pharmacy does not always supply medicines in line with their marketing authorisation. Re-packaging codeine linctus from stock bottles into smaller quantities means that the product was

Principle	Principle finding	Exception standard reference	Notable practice	Why
				not sold or supplied in accordance with its marketing authorisation.
<b>5. Equipment and facilities</b>	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 with its services. In particular, it does not have appropriate processes or up-to-date written procedures to safely govern the sale and supply of some over-the-counter medicines such as codeine linctus and Phenergan elixir. This means that there are some risks to patient safety and some vulnerable people may obtain medicines that could cause them harm. The pharmacy does not maintain all of the records that it must keep by law. So the records may not be reliable if referred to in future. And the pharmacy may not be able to investigate anomalies fully or promptly. However, members of the pharmacy team understand how to keep people's private information safe.

### Inspector's evidence

This inspection was undertaken as a result of information about unusually high purchases by the pharmacy of codeine linctus.

The superintendent pharmacist (SI) was working at the time of the inspection and the correct Responsible Pharmacist (RP) sign was displayed in the pharmacy. The SI had worked full time in the pharmacy as RP for over ten years. The pharmacy had a range of standard operating procedures (SOPs) for the services it offered. These were signed by the superintendent pharmacist (SI) when they were first implemented in 2015 but had not been reviewed since then. A part-time dispenser (the SI's husband) had signed the SOPs relevant to his role and responsibilities. The pharmacy's SOP for over-the-counter (OTC) sales of medicines was very basic and it did not include specific risks involved in selling or monitoring medicines liable to abuse or misuse such as codeine linctus. Albeit most OTC sales were made by the SI.

The SI was aware that codeine linctus was liable to abuse and explained that she received approximately one to two requests for codeine linctus each day. She commented that there had been a recent surge in over-the-counter requests for codeine linctus and Phenergan elixir. But she hadn't realised that the quantities of codeine linctus and Phenergan elixir ordered by the pharmacy were considered excessive. More people were reporting a persistent dry cough, often associated with Covid-19 and which could be very debilitating.

The SI commented that the GPs in the area had stopped prescribing OTC medicines on prescriptions for quite some time now and have been signposting people with a note to pharmacies to purchase these medicines. This included recommendations for codeine linctus to treat coughs associated with Covid-19. The SI did not keep evidence of these notes as she didn't think this was needed. The SI also stated that she refused sales of codeine linctus to people who specifically asked for it by name or if the requests were made via telephone calls.

Phenergan elixir was often requested for short-term insomnia, travel sickness and allergies. It is not indicated for treatment of Covid-19 symptoms including cough. There was evidence of the pharmacy purchasing unusually high amounts of this medicine. But the increase in supply of this product could not be explained by increased demand to treat symptoms of Covid-19. The SI had some knowledge of a current trend of combining codeine linctus with other products to make a mixture which, when taken, created a 'high-effect'.

The pharmacy did not monitor or audit the amount of codeine linctus or Phenergan elixir purchased. Doing so may have helped to highlight the relatively high volumes ordered or sold. And it didn't keep records about when requests to buy codeine linctus had been turned down.

The pharmacy's records for controlled drugs (CDs) were not maintained in line with legal requirements. The pharmacy held minimal stock of CDs. But a physical balance of an item checked at random did not match the recorded balance in the register. And records about the purchases and supplies of some CDs had not been made within the time set out in the law. The same issue had been found during a previous inspection.

The SI explained the procedure she would follow to record and report dispensing errors, and this included submitting a report to the National Reporting and Learning System. The SI said that she was able to prioritise her workload adequately and did not have many near misses or dispensing errors to report as the volume of dispensing was low. And she normally incorporated a mental break between labelling, dispensing and checking prescriptions. The SI also said that she ensured that medicines were always stored in an organised fashion to minimise picking errors when dispensing prescriptions. She was the only member of the team who was involved in ordering and putting away stock on the shelves. A current certificate of professional indemnity insurance was on display in the pharmacy.

The pharmacy's computer terminal was positioned away from public view and completed prescriptions were stored appropriately. And people's personal details were not visible to the public. An incinerator bin was used to destroy confidential waste. As found during previous inspection, a safeguarding policy was in place and details of local safeguarding agencies to escalate any safeguarding concerns were available in the pharmacy. The SI confirmed that she had completed Level 2 safeguarding training.

## Principle 2 - Staffing ✓ Standards met

### Summary findings

Members of the pharmacy team work well together and they have the appropriate skills and qualifications for their roles. The pharmacy has just about enough staff members to manage its current workload adequately.

### Inspector's evidence

The SI provided most of the RP cover in the pharmacy and was supported part-time by her husband who was a qualified dispenser. The pharmacy had no other staff members at the time of the visit. The SI was managing her dispensing workload adequately. But some routine tasks such as record keeping were not completed in a timely manner.

The pharmacy's main activity was dispensing NHS prescriptions. And it did not offer any advanced services such as MUR's or NMS's. During the pandemic, the pharmacy had reduced its opening hours from 100 hours to approximately 80 hours. The workflow in the dispensary was adequately organised albeit the dispensary was very compact and had limited space.

Subsequent to the inspection, during a telephone conversation, the SI said that she had now employed a part-time dispenser to help her with some routine tasks such as house keeping and record keeping.

## Principle 3 - Premises ✓ Standards met

### Summary findings

The premises are secure and adequate for the provision of pharmacy services.

### Inspector's evidence

The front fascia of the pharmacy appeared to be in a good state of repair. A small retail area of the pharmacy was not routinely manned. But the CCTV in the dispensary and the door chimes alerted the team members when people entered the pharmacy. The dispensary was on the first floor and it had been recently refurbished. It was clean and tidy. There was just about adequate storage and bench space to allow safe working. The dispensary was well separated from the rest of the shop and it was not accessible to members of the public. A dispensary sink for medicines preparation was clean and it had a supply of hot and cold water. Members of the pharmacy team had adequate access to hygiene facilities and the pharmacy was secured against unauthorised access when it was closed.

## Principle 4 - Services Standards not all met

### Summary findings

The pharmacy does not have adequate safeguards in place to make sure that the sales of medicines liable to misuse such as Phenergan elixir and codeine linctus are monitored and supplied safely. It does not appropriately monitor and control the sales of Phenergan elixir and codeine linctus. This means that people may receive medicines that are not safe for them to take. The pharmacy sources its medicines from licensed wholesalers. But it does not always supply medicines in line with their marketing authorisation. The pharmacy offers a very small range of healthcare services. But its prescription services are generally managed appropriately.

### Inspector's evidence

The entrance to the pharmacy was at street level and was step free. The retail area of the pharmacy was clear of slip or trip hazards and could just about accommodate a wheelchair or a pram. The pharmacy had advertised its opening hours on the door, and it had displayed a range of posters relating to Covid-19 health messages. There was a chair available for people waiting for services. The SI could speak to people in several languages including Urdu and Punjabi. And used her local knowledge to signpost people to other providers, if a service required was not offered at the pharmacy. The pharmacy did not routinely offer a prescription delivery service. But during the pandemic, the pharmacy made an exception and delivered medicines to people who were unable to attend the pharmacy in person or did not have any representatives able to collect medicines on their behalf.

The workflow in the pharmacy was organised and baskets were used during the dispensing process to prioritise workload and minimise the risk of prescriptions getting mixed up. The SI was aware of the valproate pregnancy prevention programme and knew which people needed to be provided with additional advice about its contraindications and precautions. The pharmacy currently did not have any people in the at-risk group. But it had patient information leaflets and patient cards available to supply to people when dispensing valproate. The pharmacy did not have any person currently receiving warfarin therapy. The SI was aware of ensuring therapeutic monitoring (INR) levels were within the required range before supplying warfarin to people. The SI knew that prescriptions for CDs not requiring secure storage, such as pregabalin or tramadol had a 28 day validity period and she said that prescriptions for these were generally collected within 28 days. There were no prescriptions for these items awaiting collection.

The pharmacy had decanted 2 litre stock bottles into smaller quantities and supplied to people. This was not in line with the Human Medicines Regulations 2012 as it altered the marketing authorisation of the codeine linctus, which is a Schedule 5 CD, and means its classification changed from a pharmacy (P) medicine to that of a prescription only medicine (POM).

The pharmacy ordered its stock medicines for licensed wholesalers namely AAH pharmaceuticals Ltd, Alliance and DE Midlands. And some invoices relating to purchases were kept on-site. A range of Pharmacy-only (P) medicines were stored behind the medicines counter. And some P medicines liable to abuse or misuse were stored securely in the dispensary and were not advertised in anyway. Stock medicines in the dispensary were stored in an organised manner. The pharmacy had designated bins to



store waste medicines. The SI said medicines were date checked at regular intervals and short-dated medicines were marked for removal at an appropriate time. Stock medicines were checked during the inspection and no expired medicines were found on the shelves.

Medicines requiring cold storage were kept in a refrigerator which at the time of the inspection, was operating between 2 and 8 degrees Celsius. However, the pharmacy did not keep a daily record of temperature checks. This meant that it could be difficult for the pharmacy to demonstrate that the refrigerator was operating within the required temperature range at all times. The SI said that she made a visual check each day and would take appropriate action if the refrigerator did not operate at the required range.

All CDs requiring secure storage were stored appropriately in the CD cabinet. And the pharmacy had denaturing kits available to dispose of waste CDs safely. As found during the previous inspection, the pharmacy had a process to deal with safety alerts and medicine recalls. And it kept records of action taken in response to these to maintain an audit trail. This was not checked during this inspection visit.

## Principle 5 - Equipment and facilities ✓ Standards met

### Summary findings

The pharmacy has the equipment and facilities it needs to provide its services safely. And it maintains its equipment adequately.

### Inspector's evidence

The pharmacy's computer screen was not visible from the public area of the pharmacy and its patient medication records were password protected. The SI used her own smartcard to download electronic prescriptions. The pharmacy had access to the internet and various other current reference sources such as the British National Formulary (BNF) and BNF for Children. All electrical equipment appeared to be in good working order. There were a couple of crown-stamped measures available for measuring liquid medicines and the equipment used for counting loose tablets and capsules was clean. Medicine containers were capped to prevent contamination. All private and confidential information was stored securely. Members of the pharmacy team had access to hand sanitisers and personal protective equipment including facial masks.

### 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.