General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: St. Clair Pharmacy, 231-233 St. Clair Street, Kirkcaldy, Fife, KY1 2BY

Pharmacy reference: 9011631

Type of pharmacy: Community

Date of inspection: 12/04/2022

Pharmacy context

This is a community pharmacy on a main road in a residential area of Kirkcaldy. It dispenses NHS prescriptions including supplying medicines in multi-compartment compliance packs. The pharmacy offers a repeat prescription collection service and a medicines' delivery service. It also provides substance misuse services and dispenses private prescriptions. The pharmacy team advises on minor ailments and medicines' use. And it supplies and sells a range of over-the-counter medicines. It offers services including smoking cessation, seasonal flu vaccination, and ear wax removal. This pharmacy was inspected during the COVID-19 pandemic.

Overall inspection outcome

✔ **Standards met**

Required Action: Improvement Action Plan

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 met	N/A	N/A	N/A
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 met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy mostly identifies and manages the risks associated with its services, including reducing the infection risk during the pandemic. The pharmacy team members follow some written processes for the pharmacy's services to help ensure they provide them safely. The pharmacy mostly keeps the records that it needs to by law, and it keeps people's private information safe. Team members know who to contact if they have concerns about vulnerable people. Team members discuss mistakes to learn from them, but do not record and review them, so cannot identify trends. This means team members may be missing learning opportunities.

Inspector's evidence

The pharmacy had put strategies in place to keep people safe from infection during the COVID-19 pandemic. It had hand sanitiser and screens up at the medicines' counter. Most people coming to the pharmacy wore face coverings and team members all wore masks, and they wore gloves for some activities. They also washed and sanitised their hands regularly and frequently. They cleaned surfaces and touch points daily.

The pharmacy had standard operating procedures (SOPs) which were mostly followed. One of the pharmacist directors reviewed them every two years and signed them off, although he had not done this recently. Since the last review, some of the processes in the pharmacy had changed and the SOPs had not yet been updated to reflect this. Examples included the process for the management of multi-compartment compliance packs and some record keeping. And the pharmacy had extended into adjoining premises a few weeks previously, so some dispensing processes had changed. The director pharmacist (who was present during the inspection) explained that he was due to review the SOPs and make changes as appropriate, as the new processes settled down and became embedded. Team members described and demonstrated processes they were following, and there was no suggestion that there was any risk. Most pharmacy team members had read the SOPs, and the pharmacy kept records of this. Staff roles and responsibilities were recorded on individual SOPs. Team members described their roles and accurately explained which activities could not be undertaken in the absence of the pharmacist. This very rarely occurred as the pharmacy closed for lunch, and it had not been adversely affected by pharmacist absence. The pharmacy managed dispensing, a high-risk activity, well, with coloured baskets used to differentiate between different prescription types and separate people's medication.

The pharmacy had a 'near miss' log to record dispensing errors that were identified in the pharmacy, known as near miss errors. But team members had not recorded any errors recently and they acknowledged that they had made errors in that time. This meant that they were not able to identify themes or trends and learn from them. But team members described how they corrected their own mistakes and they discussed them with the pharmacist when they were identified. They also discussed them with their colleagues, and separated some similar sounding medicines on the shelves, e.g. quinine and quetiapine. This helped them learn from mistakes. The pharmacy had a complaints procedure and welcomed feedback, although no examples were discussed.

The pharmacy had an indemnity insurance certificate, expiring 02.05.2022. The pharmacy displayed the responsible pharmacist notice and kept a responsible pharmacist log. The pharmacists described

sometimes staying late to clear dispensing backlogs, but this was not reflected in the RP log which recorded the trading hours of the pharmacy. It was a legal requirement to record accurate start and end times. The pharmacy had private prescription records including records of emergency supplies and veterinary prescriptions. It kept unlicensed specials records and controlled drugs (CD) registers with running balances maintained but not all regularly audited. It had a CD destruction register for patient returned medicines, but this was not used. The team used CD registers to record patient returns and destructions.

Pharmacy team members were aware of the need for confidentiality. They had all read a SOP. They segregated confidential waste for shredding which they tried to carry out daily to avoid a build-up of confidential information. No person identifiable information was visible to the public. Team members had also read a SOP on safeguarding. They knew how to raise a concern locally and had access to contact details and processes. The pharmacists were registered with the Disclosure Scotland 'Protecting Vulnerable Groups' (PVG) scheme.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough qualified and experienced team members to safely provide its services. They make decisions within their competence to provide safe services to people. And they know how to make suggestions and raise concerns if they have any to keep the pharmacy safe. But the pharmacy does not routinely set aside time for team members to continue their learning so they may find it difficult to keep their knowledge up to date.

Inspector's evidence

The pharmacy had a full-time pharmacist manager and a second pharmacist on the three busiest days of the week, a pharmacy technician (PT) four days per week, three full-time and one part-time dispensers, two part-time medicines counter assistants (MCA) (four afternoons per week, and one and a half day per week), and one full-time and one part-time delivery drivers. At the time of inspection there were two pharmacists, one pharmacy technician, three dispensers and one MCA. Team members were able to manage the workload. But there were challenges at busy times, and dispensing volume had increased significantly during the pandemic. The pharmacy had recruited recently and increased the size of the team due to the increased workload and larger space. And it was currently recruiting for one more full-time team member. The second pharmacist was usually an employed relief pharmacist or one of the pharmacist directors. This provided continuity with all pharmacists familiar with the processes in the pharmacy. All team members were qualified for their roles, and the pharmacy technician was soon to start an accuracy checking course. This would benefit the pharmacy in the longer term. The delivery drivers had been in their roles for a few months and were not yet registered on their mandatory training.

The pharmacy did not currently provide learning time during the working day for team members to undertake regular training and development. It had been challenging recently with the demands of the pandemic, the large increase in dispensing, and building work. The pharmacy technician described reading relevant material when the opportunity arose. And she and the pharmacists undertook regulatory re-validation activities. Recently all team members had undertaken annual training as part of the requirement of the pharmacy's Wholesale Dealer's Licence.

Team members were observed going about their tasks in a systematic and professional manner. They asked appropriate questions when supplying medicines over the counter and referred to the pharmacist when required. They were all competent to provide aspects of the NHS Pharmacy First service and made appropriate decisions regarding treatment and providing advice to people to manage their symptoms. The pharmacists described being confident that team members worked within their competence and referred people as required. Team members demonstrated an awareness of repeat requests for medicines intended for short term use. And they dealt appropriately with such requests.

Pharmacy team members understood the importance of reporting mistakes and were comfortable owning up to their own mistakes. They had an open culture environment in the pharmacy where they shared and discussed these at the time. They described feeling able to make suggestions and raise concerns to the pharmacist manager or either of the pharmacist directors. And they gave appropriate responses to scenarios posed. The company did not set targets but encouraged team members to offer services to people who would benefit from them.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises are clean and suitable for the pharmacy services provided. The pharmacy has suitable facilities for people to have conversations with team members in private. The pharmacy is secure when closed.

Inspector's evidence

These were average-sized premises incorporating a retail area, dispensary, storage space and staff facilities. The pharmacy had doubled in size recently as it had extended into an adjacent retail unit. It had been providing pharmacy services from the double unit for around two months. There was still some work to be completed such as furnishing consultation rooms, replacing the external fascia, building shelves for storage, and some organisation within the dispensary and storage areas. The pharmacy was currently using the toilet and one of the consultation rooms for storage. The premises were clean, and basically well maintained. There were sinks in the dispensary, staff area and toilet. These had hot and cold running water, soap, and clean hand towels. And there was hand sanitiser available throughout the premises.

People were not able to see activities being undertaken in the dispensary. The pharmacy had two consultation rooms. One which only had a door from the retail area was not in use currently due to being used for storage. The other also had a door from the dispensary and was in use. It was not yet fully furnished, but had two chairs, enabling people to sit during consultations with team members. The doors closed providing privacy. The pharmacy also had a separate area for specialist services such as the delivery of substance misuse services. People accessed a lobby directly from the street, then called a phone in the dispensary to gain access into the service area. A pharmacy team member answered the phone and admitted the person remotely as appropriate. There was a hatch between this area and the dispensary that team members opened to enable them to speak to people and deliver the required service. Temperature and lighting felt comfortable throughout the premises.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy helps people to access its services which it provides safely. Pharmacy team members follow written processes relevant to the services they provide. They usually support people by providing them with suitable information and advice to help them use their medicines. And they provided extra written information to people taking higher risk medicines. The pharmacy obtains medicines from reliable sources and mostly stores them correctly. Pharmacy team members know what to do if medicines are not fit for purpose.

Inspector's evidence

The pharmacy had good physical access by means of a level entrance and team members assisted people with the door if necessary. The pharmacy listed its services and had leaflets available on a variety of topics. It had a hearing loop in working order for people wearing hearing aids to use. And it could provide large print labels for people with impaired vision. The pharmacy provided a delivery service to people who had difficulty coming to the pharmacy.

Pharmacy team members followed a logical and methodical workflow for dispensing. They used coloured baskets to differentiate between different prescription types and separate people's medicines and prescriptions. Prescriptions followed a cyclical journey around the dispensary with defined areas for labelling, dispensing, and checking. Due to the volume of prescriptions, often two team members labelled at a time. They used a faster computer to label prescriptions for multiple items, and another team member used a slower computer for smaller prescriptions. Team members highlighted changes to medication to the pharmacist to enable them to carry out a meaningful clinical assessment. The pharmacist explained that by the end of the day, all that day's prescriptions were completed. This ensured that people's medicines were ready as they expected. There had been occasions when a pharmacist and team member had worked late to complete any outstanding dispensing or checking. Team members mostly initialled dispensing labels to provide an audit trail of who had dispensed and checked medicines. Sometimes they did not do this on some medicines supplied by instalment. The pharmacy usually assembled owings later the same day or the following day.

Some people received medicines from 'Medicines Care Review' (MCR) serial prescriptions. The pharmacy dispensed these when people requested them. The labelling system automatically labelled all items due, even if the person did not request all items. The pharmacy retained the labels to use at a future date should the person subsequently request them. Team members explained this did notr happen often. But if these labels were used later, they would have the wrong dispensing date on them which could be misleading. But the pharmacy team did not discuss with people the reason that they did not request all items. Examples included medicines used to prevent angina that people should only stop taking on medical advice. And the pharmacy placed dispensed medicines onto retrieval shelves where they may remain for up to two months. The team did not have a process to monitor compliance or discuss medication with people. This was partly attributed to how busy the pharmacy had become as dispensing volume had increased. The pharmacist was not carrying out pharmaceutical care needs' assessments, so opportunities to address pharmaceutical care issues may be missed.

The pharmacy managed the dispensing and the related record-keeping for multi-compartment compliance packs on a four-weekly cycle. It kept relevant records for people it supplied these packs to

including medication changes. Some prescribers provided the pharmacy with an NHS Fife medication change template which usually stated when the change was to take effect which was helpful for the pharmacy. The pharmacy kept these if it received them. The company operated a 'hub and spoke' model, whereby another pharmacy, the hub, assembled the packs and sent them back to this pharmacy, the spoke. The pharmacy had told people that the packs were assembled at another branch, and the addresses of both branches were on the backing sheets affixed to the packs. The hub used a dispensing robot to fill the packs, and it included photos of medication on the backing sheets which helped people identify their tablets. A trained team member put the information from prescriptions into a computer system in a similar manner as labelling other prescriptions. A pharmacist checked the input for accuracy and carried out a clinical assessment before transmitting the data to the hub. But the pharmacy did not keep a record of who had carried out these tasks. When the packs were assembled at the hub, a dispenser and an accuracy checking pharmacy technician (ACPT) checked the pack for accuracy, and they both initialled the backing sheets to provide an audit trail. This pharmacy (spoke) stored completed packs on dedicated shelves by day of supply. It followed a logical system which visually identified when the next dispensing cycle began. The hub clearly labelled packs with people's details, date of supply and instalment number, both on the backing sheet and on the pack spine which helped team members select the correct pack for supply. This pharmacy (spoke) assembled some packs rather than sending them to the hub. These included packs containing medicines with limited stability once removed from original packaging, and some for medicines that were not suitable to be stored in the robot. The pharmacy supplied patient information leaflets (PILs) with the first pack of each prescription.

The pharmacy supplied a variety of other medicines by instalment. A team member dispensed most of these prescriptions in their entirety when the pharmacy received them. And depending on the storage requirements, a team member dispensed some medicines the day before supply. The pharmacist checked the instalments and placed the medicines in bags labelled with the person's details and date of supply. They were stored alphabetically in individually named baskets. A team member assembled medicines for supervised consumption in the pharmacy, as people came to the pharmacy. A pharmacist checked the dose then a trained dispensing team member supervised the consumption at the hatch in the supervision area. They did not attach labels to some people's supervised medicines which did not comply with labelling regulations for the supply of medicines. And it meant that people did not have the opportunity to see the details on their label.

A pharmacist undertook clinical checks and provided appropriate advice and counselling to people receiving high-risk medicines including valproate, methotrexate, lithium, and warfarin. They or a team member supplied written information and record books if required. The pharmacy had put the guidance from the valproate pregnancy prevention programme in place. The pharmacy followed the service specifications for NHS services and patient group directives (PGDs) were in place for unscheduled care, Pharmacy First, smoking cessation and emergency hormonal contraception. The pharmacy team members were trained to deliver the Pharmacy First service within their competence and under the pharmacist's supervision. They used the sale of medicines protocol and the formulary to respond to symptoms and make suggestions for treatment. They referred to the pharmacist as required. The pharmacy supplied naloxone to eligible people under a service level agreement. The pharmacists had completed training to provide the service. And the pharmacy provided the NHS needle exchange service. All team members were trained to deliver this service and make the required records. They encouraged people to return used equipment and supplied them with disposal containers. The pharmacy had offered all team members hepatitis B vaccination. During the flu season the pharmacy offered NHS and private flu vaccination following PGDs. And it was in the process of setting up the new NHS pharmacy travel service. The pharmacy provided a private ear wax removal service which was growing in popularity as most GP practices were not currently offering ear syringing. The regular

pharmacist, regular relief pharmacist and one dispenser were trained and competent to deliver this service.

The pharmacy obtained medicines from licensed wholesalers such as Alliance and AAH. The pharmacy stored medicines in original packaging on shelves, in drawers and in cupboards. The pharmacy stored items requiring cold storage in two fridges and team members monitored and recorded minimum and maximum temperatures daily. They took appropriate action if there was any deviation from accepted limits. Team members checked expiry dates of medicines and those inspected were found to be in date. The pharmacy protected pharmacy (P) medicines from self-selection. Team members followed the sale of medicines protocol when selling these.

The pharmacy actioned Medicines and Healthcare products Regulatory Agency (MHRA) recalls and safety alerts on receipt and kept records. Team members contacted people who had received medicines subject to patient level recalls. They returned items received damaged or faulty to suppliers as soon as possible.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to deliver it services. And team members look after the equipment to ensure it works.

Inspector's evidence

The pharmacy had resources available including current editions of the British National Formulary (BNF) and BNF for Children. It had Internet access allowing online resources to be used.

The pharmacy kept equipment required to deliver pharmacy services in the consultation room where it was used with people accessing its services. This included a carbon monoxide monitor maintained by the health board, and suction equipment for the removal of ear wax. Team members were trained to use this and maintained and cleaned it following the manufacturer's guidance. The pharmacy kept crown-stamped measures by the sink, and separate marked ones were used for methadone. The pharmacy used an automatic pump for measuring methadone solution. Team members cleaned it at the end of each day and poured test volumes each morning when they set it up for the day. The pharmacy team kept clean tablet and capsule counters in the dispensary.

The pharmacy stored paper records in the dispensary inaccessible to the public. It stored prescription medication waiting to be collected in a way that prevented patient information being seen by any other people in the retail area. Team members used passwords to access computers and did not leave them unattended unless they were locked.

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.