General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Wemyss Pharmacy, Unit 2 21 Main Road, East

Wemyss, KIRKCALDY, Fife, KY1 4RE

Pharmacy reference: 1117359

Type of pharmacy: Community

Date of inspection: 26/06/2021

Pharmacy context

This is a community pharmacy beside other shops in a village. It dispenses NHS prescriptions including supplying medicines in multi-compartment compliance packs. And it supplies medicines to care homes. 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 supplies a range of over-the-counter medicines.

Overall inspection outcome

Standards not all 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 Governance	Standards not all met	1.1	Standard not met	Standard operating procedures are out of date, do not reflect processes in the pharmacy and are not all being followed. This is creating significant risk.
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 not all met

Summary findings

The pharmacy has written processes in place to help ensure that its services are provided safely, but they have not been reviewed for several years. And some of these documents do not reflect the processes in the pharmacy and some team members have not read them so are not following them. So, there is a risk of mistakes. Team members briefly record some but not all mistakes that they make to learn from them. But they don't review these regularly to identify common themes. So, they could be missing learning opportunities. The pharmacy keeps the records that it needs to by law and keeps people's private information safe. Team members know how to find information about who to contact if they have concerns about vulnerable people.

Inspector's evidence

The pharmacy had put some strategies in place to keep people safe from infection during the COVID-19 pandemic. It had screens up at the medicines' counter and it allowed two people on the premises at any time. Most people coming to the pharmacy wore face coverings and team members all wore masks when speaking to people using the pharmacy. But they did not wear them fully covering their nose and mouth when working in the dispensary. Some but not all the time they were able to socially distance from each other. They did not wash or sanitise their hands during the inspection. And the team did not clean the consultation room after use during the inspection. Team members did not think personal risk assessments had been carried out.

The pharmacy had standard operating procedures (SOPs) which were put in place by the superintendent pharmacist (SI) in 2017 following the last inspection. And some were from 2016. They had review dates of 2018 and 2019 but there was no evidence of review. Some team members had read and signed them including the pharmacy manager who was not present during the inspection. But one of the dispensers present had not signed any, and the other trainee dispenser had only signed a few. She explained that she had read, and signed SOPs as recommended while undertaking an accredited dispenser course. She had been in the pharmacy for two years. The team did not follow all the SOPs, such as near miss errors. And some SOPs did not explain the process to follow, such as the management of multi-compartment compliance packs and management of serial prescriptions. The controlled drug (CD) SOP for instalment prescriptions referred to checking the correct prescription form was used – this was not relevant in Scotland. And it stated that certain people using pharmacy services must sign a four-way agreement with the pharmacy, which was not done. It referred to 'regular' CD register running balance audits, so not describing the process or how often to do this. Team members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist. They were currently working on ensuring all team members could competently undertake all tasks. 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 did not have a business continuity plan to address maintenance issues or disruption to services. But it had phone numbers accessible for suppliers and other healthcare professionals.

Team members used 'near miss logs' to record some dispensing errors that were identified in the pharmacy, known as near miss errors. But they did not record a lot of information. And the 'action taken' column was populated with 're-dispensed' rather than any changes to avoid repetition. The

pharmacy had a SOP for dealing with dispensing errors, but team members were not aware of it and explained that the pharmacist dealt with any errors. Although none were described. The SOP was not being followed. The pharmacy had a complaints procedure and welcomed feedback. But there were no examples.

The pharmacy had an indemnity insurance certificate, expiring 31 May 2022. The pharmacy displayed the responsible pharmacist notice and had an accurate responsible pharmacist log. The team explained that the pharmacy had electronic private prescription records including records of emergency supplies and veterinary prescriptions. But team members did not know how to access this record, so it was not seen during the inspection. It kept unlicensed specials records and controlled drugs (CD) registers with running balances maintained and sometimes audited. Dates of audits observed over the past 18 months were 11/19, 05/20, 08/20, 03,21, 05/21. Typically, pharmacies carried this out weekly or monthly. One CD register had a page missing (Elvanse 70mg). The pharmacy had a CD destruction register for patient returned medicines.

Pharmacy team members were aware of the need for confidentiality. The pharmacy had a SOP which had been implemented in 2017 and signed by four team members at that time. The current pharmacy manager and the dispensers present during the inspection had not signed it. One dispenser had good awareness from her previous employment and the other from her coursework. They segregated confidential waste for shredding. No person identifiable information was visible to the public. Similarly, some team members had also read and signed a SOP on safeguarding. But it was short on process and was more like a training document. The process was to contact the SI and signpost people to organisations such as NSPCC. There was no information about how to raise a concern locally, and team members present were not clear where to find this information. But they explained that they had some knowledge on the subject from their courses, and they could find local information on the Community Pharmacy Scotland website.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough qualified and experienced team members to safely provide its services. Team members can make decisions within their competence to provide safe services to people. They know how to make suggestions and raise concerns if they have any to keep the pharmacy safe. The pharmacy gives them time during the working day to complete course work. But they do not have time set aside to keep their knowledge and skills up to date. This could affect how well they care for people and the advice they give.

Inspector's evidence

The pharmacy had the following staff: one full-time pharmacist manager, two full-time and three part-time dispensers, a part-time delivery driver. The pharmacy displayed some certificates of qualification and competence in services. Typically, there were four or five team members and the pharmacist working at most times during the week, and two and a pharmacist on Saturdays. Team members were able to manage the workload. But it had been challenging over the past few months as one of the full-time team members had been absent for some time. The part-time team members had different work patterns and were sometimes able to work flexibly to cover absence. Two part-time dispensers were undertaking dispensing training and had already completed medicines counter courses. The pharmacy provided some time during the working day for training, and team members undertook some at home. In 2017 the pharmacy had sourced online training modules and team members at that time had signed a SOP about how these would be used. This was not currently in place and the team members present had not signed the SOP. They had signed up to the online platform but never used it.

Although SOPs were not a reflection of processes in the pharmacy, team members were observed going about their tasks in a systematic and professional manner. They were empowered and competent to deal with some issues autonomously. For example, they contacted the GP practice regarding issues such as unsigned prescriptions. They always documented this and told the pharmacist the outcome. They asked appropriate questions when supplying medicines over the counter and referred to the pharmacist when required. They 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 errors. They had an open environment in the pharmacy where they could share and discuss these. They could make suggestions and raise concerns to the superintendent pharmacist (SI). For example, there had been a problem with the lights in the pharmacy a few months ago. After team members had brought this to his attention the SI had them repaired promptly. And recently they had notified him about a problem with hot water and there was planned maintenance for this. The team did not have formal meetings, but team members discussed any issues and shared information continually as they worked.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is safe and clean and suitable for the services it provides. It has suitable facilities for people to have conversations with team members in private.

Inspector's evidence

These were average-sized premises incorporating a retail area, dispensary and rear area including storage space and staff facilities. The premises were clean, hygienic and well maintained. There were sinks in the dispensary, staff room and toilet. These had hot and cold running water, soap, and clean hand towels.

People were not able to see activities being undertaken in the dispensary. The pharmacy had a consultation room with a table and chair which was clean, and the door closed providing privacy. As this room was not large enough to allow social distancing the team was using it infrequently. It had a hatch through to the dispensary, so the pharmacist could supervise people taking their medication safely. Temperature and lighting were comfortable.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy helps people to access its services which it provides safely. Pharmacy team members support people by providing them with suitable information and advice to help them use their medicines. And they provide extra written information to people taking higher-risk medicines. The pharmacy obtains medicines from reputable sources and stores them appropriately. Team members do not always follow written process for the services they provide. This could mean that they don't all carry out tasks in the same way which could lead to mistakes.

Inspector's evidence

The pharmacy had good physical access by means of a ramp at the entrance and team members helped people with the door if required. 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.

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. They shared information with the pharmacist such as changes or new items. They either did this verbally at the time of labelling or they attached a note to the prescription. Team members initialled dispensing labels to provide an audit trail of who had dispensed and checked all medicines. The pharmacy usually assembled owings later the same day or the following day.

Some people received medicines from 'Medicines Care Review' (MCR) serial prescriptions. This service was currently increasing as pharmacist independent prescribers working with GP practices were initiating serial prescriptions. The pharmacy had not yet developed a robust process for this service, but team members were discussing it with a view to devising a process. The SOP for serial prescriptions did not define a process. The pharmacy did not yet have a way of monitoring compliance or undertaking medication reviews. The pharmacist had previously undertaken some medication reviews for the chronic medication service (the predecessor of MCR) but had not completed the signature and date fields. So, it was not known when these had been done.

The pharmacy managed the dispensing and the related record-keeping for multi-compartment compliance packs on a four-weekly cycle. Team members assembled four weeks' packs at a time, one week before the first pack was due to be supplied. They ordered prescriptions the week before that to ensure there was plenty of time to follow-up any issues. The process was robust and organised, although not specified in the SOP. Team members supplied patient information leaflets monthly. And they included tablet descriptions on backing sheets for some items, mainly packs for people in a care home. The pharmacy supplied four packs at a time to some people if they had requested this. But prescriptions stated, 'dispense weekly' and there was no evidence of prescribers authorising this. The pharmacy stored completed packs in an orderly manner, and they were appropriately labelled with day and method of supply.

A pharmacist undertook clinical checks and provided appropriate advice and counselling to people receiving high-risk medicines including valproate, methotrexate, lithium, and warfarin. She 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. Team members present during the inspection did not think there were any people in the high-risk group receiving valproate. The pharmacy followed the service specifications for NHS services. It had patient group directions (PGDs) in place for unscheduled care, the Pharmacy First service, smoking cessation, and emergency hormonal contraception (EHC). 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. During the pandemic the pharmacist had delivered some services remotely by phone. This had ensured service delivery while minimising footfall on the premises. Services delivered in this way included smoking cessation, urinary tract infection (UTI) treatment and supply of emergency hormonal contraception (EHC). The pharmacist carried out the consultation remotely and if appropriate, the team prepared medication ready for collection when the person came to the pharmacy.

The pharmacy obtained medicines from licensed wholesalers such as Ethigen, Alliance and AAH. The pharmacy stored medicines in original packaging on shelves, in drawers and in cupboards. And team members used space well to segregate stock, dispensed items and obsolete items. The pharmacy stored items requiring cold storage in a fridge 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 regularly 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 its services.

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 had a carbon monoxide monitor maintained by the health board, but the team was not using this during the pandemic to reduce the chance of spreading infection. Team members kept crown-stamped measures by the sink in the dispensary, and separate marked ones were used for methadone. And they had clean tablet and capsule counters including a separate marked one for cytotoxic tablets.

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.	