General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Apple Pharmacy, 65-67 Dalry Road, EDINBURGH, Midlothian, EH11 2BZ

Pharmacy reference: 1042651

Type of pharmacy: Community

Date of inspection: 12/06/2019

Pharmacy context

This is a community pharmacy on a street with other shops close to a city centre. People of all ages use the pharmacy. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It also supplies medicines in multi-compartment compliance packs. The superintendent pharmacist works full-time in the pharmacy.

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	The pharmacy does not have adequate standard operating procedures for all activities. It does not have audit trails for dispensing. Some activities are delivered by untrained team members.
		1.2	Standard not met	The pharmacy does not check and review dispensing accuracy so team members cannot learn from mistakes and make improvements.
		1.7	Standard not met	The pharmacy does not always protect people's personal information. Some items are not securely disposed of.
2. Staff	Standards not all met	2.1	Standard not met	The pharmacy does not have sufficient staff.
		2.2	Standard not met	Some pharmacy team members are carrying out activities that they have not been trained for. And they are not always supervised. The pharmacy does not provide training material or time for developing skills.
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 does not deliver all services safely. Some dates are incorrect on multi-compartmental compliance packs, and the backing sheets are not attached. The pharmacy does not have audit trails in place for dispensing
		4.3	Standard not met	The pharmacy does not supply all medicines safely. People are not asked for identification when collecting some medicines, so the wrong medicine or wrong quantity of medicine could be supplied.
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 documented processes for team members to follow for all activities. They do not have a process in place to keep each person's dispensed medicines separate. So, there is a risk of mistakes. Team members do not record mistakes, so they are missing learning opportunities. This means they cannot improve and reduce mistakes. Team members do not sign labels on medicines so if there was a query about these, it would be difficult to know who to ask about it. The pharmacy keeps the records that it needs to by law but doesn't always audit these as recommended. The pharmacy keeps some people's information safe, but some information is included in general waste. Team members do not all know how to protect vulnerable people.

Inspector's evidence

The pharmacy had standard operating procedures (SOPs) for some activities. It did not have SOPs for the management of controlled drugs or multi-compartmental compliance packs. They had been written nine years previously. The superintendent pharmacist had reviewed them over the past few years but not made any changes or updates. Most team members had read and signed SOPs, but the locum pharmacist working during the inspection and a team member from another branch had not. The SOP 'Dealing with incidents (including dispensing errors and near misses)' did not describe any process for recording and reviewing near misses/errors.

The pharmacy did not use baskets to segregate patients' medicines during the dispensing process. Prescriptions were left on top of dispensed medicines for the pharmacist to check. Different patients' dispensed medicines and prescriptions were laid out on a bench with a small space between them. The superintendent pharmacist explained that there had not been any errors caused because of this. Pharmacy team members did not sign dispensing labels so there was no audit trail to identify who had dispensed or checked medicines. The pharmacy did not record near miss errors or errors reaching patients. Team members could not provide details of any errors or improvements made to reduce these.

Pharmacy team members who had not undertaken any formal training were involved in many tasks, including supervised supply of methadone instalments. There was a complaints procedure in place. Indemnity insurance certificate was in place, expiring April 2020.

The following records were maintained in compliance with relevant legislation: Responsible Pharmacist notice displayed; Responsible pharmacist log; Private prescription records including records of emergency supplies and veterinary prescriptions; Unlicensed specials records; Controlled drugs registers, with running balances maintained; Controlled drug (CD) destruction register for patient returned medicines. The electronic patient medication records were backed up each night to ensure no data was lost.

Team members described awareness of confidentiality. Some team members thought they had read something on the topic, and others had not. They segregated confidential waste for secure destruction. But methadone bottles with patient details on them were placed in normal plastic recycling.

Pharmacy team members who were asked, did not know how to raise safeguarding concerns. The locum pharmacist did not know how to raise concerns locally. He was PVG registered, but not linked to this employment.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy does not have enough trained or training staff members. So, they may not all be competent for the tasks they are undertaking. They do not have the experience to be able to make professional judgements or raise concerns. Trained team members do not have regular training time to develop their skills and knowledge.

Inspector's evidence

Staff numbers working in the pharmacy were: One full-time pharmacist (superintendent pharmacist); One locum pharmacist providing occasional double cover while there were staffing challenges; One full-time dispenser; One part-time dispenser, working four mornings per week; One part-time medicines counter assistant working Saturday mornings and Friday afternoons (student); One student on a zero hours contract who had just been enrolled on the medicines' counter/dispensary assistant course, but not yet started it; One student hoping to study pharmacy who had only worked one day previously in this pharmacy, and a few weeks in another pharmacy. He was not registered on any course.

The pharmacy had experienced staffing challenges over the past few months following absence and the loss of a pharmacy technician and another team member. The superintendent pharmacist described a situation when in a short period of time five team members had been reduced to two. The pharmacy had installed a new computer system around this time which further challenged the team.

The pharmacy had recruited students, some on a temporary basis to address the shortfall. It was in the process of making some positions permanent and registering team members onto accredited courses. The skills mix, and staffing level was not yet satisfactory as there were insufficient trained or training team members. During the inspection untrained staff were not fully supervised by the locum pharmacist who was unfamiliar with the pharmacy. He had not signed standard operating procedures and was following processes in the pharmacy that were not appropriate e.g. the management and supply of some instalment prescriptions. Untrained team members were supplying medicines without the expected checks in place e.g. not asking for identification, not using the sale of medicines protocol effectively, and advising on minor ailments then printing prescriptions and dispensing them.

The pharmacy was not providing any protected learning time or training or development for any team members. There was no evidence of team members providing feedback or raising concerns. The dispensers could own up to their own mistakes but did not record these. Targets were not set.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is suitable for its services. Pharmacy team members use a private room for some conversations with people. They also use a discreet area for some services. People cannot overhear private conversations. The pharmacy is secure when closed.

Inspector's evidence

These were average sized premises with a large basement. The basement incorporated storage, a staff area and an additional dispensary where multi-compartmental medicines packs and instalment dispensing was undertaken. There were sinks in the dispensary, staff room and toilet. These had hot and cold running water, soap, and clean hand towels. The premises were observed to be mostly clean.

People were not able to see activities being undertaken in the dispensary. Prescription medication waiting to be collected was stored in a way that prevented patient information being seen by any other patients or customers.

There was a consultation room with a desk, chairs, sink and computer which was also used as an office. The door closed providing privacy. A dispenser used this room for a smoking cessation consultation during the inspection. The pharmacy had a discreet area with a hatch to the dispensary for the delivery of substance misuse supervision. Temperature and lighting were comfortable.

Principle 4 - Services **Standards not all met**

Summary findings

The pharmacy helps people to ensure they can all use its services. The pharmacy team provides some services safely. But team members do not always follow written processes. They do not always check that they are giving medicine to the correct person. And some team members are not trained for the services. Some people get their medicines supplied in packs that help them take their medicine. The pharmacy is not following a documented process for this and dates on some packs are wrong which could be confusing. The sheets with tablet names and instructions are not attached to packs, so could be lost. This means people might not know the name of their medicines or when they should take them. Some pharmacy team members give people information to help them use their medicines. They provide extra written information to people with some medicines. But not all team members are aware of medicines and the advice involved so some people might not get the information they need.

Inspector's evidence

The pharmacy was accessed by a wide door and flat entrance. Team members gave assistance with the door when required. The pharmacy displayed a list of its services. Team members provided large print labels for people with impaired vision.

Dispensing workflow was logical with designated areas for dispensing and checking. But dispensed medicines were left lying on a bench to be checked, with different patients' medicines separated by a small space. The pharmacy did not use baskets to separate these. Team members did not have a process in place to highlight changes or omissions to the pharmacist. This made it difficult for a pharmacist to undertake a clinical check, especially a locum pharmacist unfamiliar with patients. The pharmacy team members did not sign dispensing labels so there was not an audit trail of who had dispensed and checked items.

The pharmacy provided a delivery service and the driver obtained signatures from people on receipt of controlled drugs. The pharmacy managed multi-compartment compliance packs on a four-weekly cycle with four assembled at a time. The part-time dispenser usually assembled these. The superintendent pharmacist had recently been involved and he had reviewed the process making some improvements. There was no documented standard operating procedure for this process, but the process described was robust and thorough. Team members not familiar with this pharmacy would not have a documented process to follow. Patients were divided into four groups and records kept of which patients' medicines were managed in which week. A chart on the wall provided detail of the different weeks. Completed trays were stored in patient named sealed boxes by day of supply and week number. Backing sheets had start date on them but these were not firmly attached to packs, meaning that there was a high risk of them being lost or discarded while packs were in use. Some backing sheets had incorrect dates on them – one was seen with a date in May and another from the beginning of June, the week before the inspection. This meant people had been supplied with trays with the incorrect date on them which could be confusing for carers or others. The pharmacy supplied patient information leaflets with the first pack of each prescription. The dispenser placed assembled trays into a small lift to be taken to the dispensary for the pharmacist to check. The pharmacist sealed trays at the point of checking. The pharmacy kept thorough and robust records of any changes on the electronic patient medication record. Most packs inspected had initials of personnel who had dispensed and checked.

The full-time dispenser managed other instalment prescriptions. The pharmacy provided a lot of patients with medicines by instalment. The dispenser assembled prescriptions in their entirety, and a pharmacist checked the instalments. Then he bagged and labelled instalments for individual patients and placed them in boxes by date. These were stored in the basement and taken to the dispensary each day. The pharmacy kept the prescriptions in the dispensary. Instalments inspected had a pharmacist's signature but not a dispenser's signature on the labels.

A dispenser poured methadone instalments weekly and these were checked by a pharmacist, but there were no signatures on labels. Most bottles required two labels, and they were attached in such a way that some directions were obscured. They were stored in a controlled drug (CD) cabinet and each morning that day's instalments were removed from the cabinet and placed on a dispensing bench adjacent to it. The pharmacist was not able to clearly see that area from the checking bench, so instalments were not under his personal control.

All team members, including those very new to the pharmacy and untrained, supplied methadone instalments to people. They did not ask for identification and some supplies were made with nothing said to patients. When asked, team members said that they knew all the patients. There was no SOP for them to follow. The locum pharmacist explained that he just followed the process already established in the pharmacy that he was working in. The members discarded used methadone bottles into a bucket in the dispensary without draining bottles or removing dispensing labels with patient identifiable information on them. They explained that they placed these into plastic recycling.

The part-time dispenser was aware of the valproate pregnancy prevention program and knew a search had been undertaken. One person had been identified and she was appropriately counselled each time the medicine was supplied. Other team members were not aware of this. Team members had limited awareness of information to be supplied to people receiving high risk medicines.
The pharmacy followed the service specifications for NHS services, and patient group directions (PGDs) were in place for unscheduled care, pharmacy first, smoking cessation, emergency hormonal contraception, chloramphenicol ophthalmic products and chlamydia treatment.

The pharmacy was not actively involved in delivering the chronic medication service (CMS). The superintendent pharmacist believed until recently that the service had stopped. But he had recently attended a meeting at a local GP practice with a view to re-implementing it. He was not routinely registering patients for the service.

Pharmacy team members were empowered to deliver the minor ailments service (eMAS) within their competence, despite being untrained. Appropriate responses were given to a scenario posed.
The part-time dispenser mostly delivered the smoking cessation service. She described enjoying this and had had some recent successes. Three people had recently completed the program, to successfully. During the inspection she undertook an initial consultation with a new patient.

Invoices were observed from licensed suppliers such as Phoenix, AAH, Alliance, and Eclipse. The pharmacy did not comply with the requirements of the Falsified Medicines Directive (FMD). Team members were not aware of this. Medicines inspected were found to be in date, and team members described undertaking date checking. They did not keep records of this – records from 18 months previously were observed. Medicines were stored in original packaging on shelves/in cupboards. Items requiring cold storage were stored in a fridge with minimum and maximum temperatures monitored and action taken if there was any deviation from accepted limits.

The pharmacy protected pharmacy (P) medicines from self-selection.

MHRA recalls and alerts were actioned on receipt and records kept. The pharmacy contacted any people who had received medicines subject to a patient level recall. Items received damaged or faulty were returned to suppliers as soon as possible.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs for the delivery of its services. It looks after this equipment to ensure it works.

Inspector's evidence

The pharmacy had texts 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 equipment it required to deliver its services. This included Crown stamped measures, a hand pump used for pouring methadone which was cleaned and calibrated at each use, and tablet and capsule counters including a separate one for cytotoxic tablets. It kept these in the dispensary where they were used bring the assembly of medicines. The pharmacy also had a carbon monoxide monitor which was maintained by the health board. It stored it in the consultation room where it was used with people accessing the smoking cessation service.

The pharmacy kept paper records in the dispensary and basement, inaccessible to the public. Pharmacy team members never left computers unattended and used passwords. They took care to ensure that screens were not visible to the public. The pharmacy had recently installed a new computer system to improve patient records and the labelling system. It had both systems available at the time of inspection during the transition.

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.