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: 13/02/2020

Pharmacy context

This is a community pharmacy on a street with other shops close to a city centre. It dispenses NHS prescriptions including supplying medicines by instalment and in multi-compartment compliance packs. The pharmacy offers a repeat prescription collection service and a medicines' delivery service. It also provides substance misuse services, the NHS smoking cessation service and dispenses private prescriptions. The pharmacy team advises on minor ailments and medicines' use. And supplies a range of over-the-counter medicines. 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	1.6	Standard not met	The pharmacy does not keep all records as required by legislation and standard good practice. These include missing records for private prescriptions since July 2019. And incorrect entries for controlled drugs. The pharmacy hasn't adequately investigated discrepancies in running balance records.
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 procedures for the team members to follow to help make sure its services are delivered safely. But the pharmacy doesn't keep all the records as required by legislation and good practice. So it may be difficult to resolve errors and queries. The team members record mistakes and show some learning from these mistakes. They listen to people's feedback to improve services. The pharmacy team members keep people's private information safe. And they help to protect vulnerable people.

Inspector's evidence

The pharmacy has made improvements since the last inspection, in terms of the availablity of standard operating propcedures, monitoring of errors for learning, and team members receiving training on confidentiality.

The pharmacy had standard operating procedures (SOPs) which were followed for some activities and tasks. But team members did not follow processes for some record keeping. Pharmacy team members had read them, and the pharmacy kept records of this. Most SOPs had been prepared several years ago by a pharmacist who used to work in another part of the business. The pharmacy superintendent reviewed them last year and signed them off. Staff roles and responsibilities were recorded on a specific SOP. This was an improvement from the previous inspection when there were inadequate SOPs which did not cover all activities in the pharmacy. Team members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist. Most experienced and trained team members were competent to undertake all activities in the pharmacy. Most of the pharmacy's dispensing was multicompartment compliance packs, instalment prescriptions and substance misuse prescriptions. The pharmacy acknowledged the higher risk involved with some of this dispensing and used a separate area of the pharmacy to manage instalment dispensing.

Team members used near miss logs to record dispensing errors that were identified in the pharmacy. The pharmacist usually recorded these. He documented action taken for most incidents as 'education'. He explained that he looked at these regularly but had not identified any trends or patterns. Records observed during the inspection related to incorrect quantities or forms, or inexperienced staff. The pharmacist explained that he discussed incidents with team members at the time. The team had not made any changes to avoid repetition of events. Most of the errors made were due to inexperience. Trainee staff dispensed most walk-in and collection service prescriptions. Experienced dispensers managed instalment prescriptions, including those for multicompartment compliance packs. The pharmacist explained that they did not make many errors. He attributed this partially to them working in a room in the basement where there was little or no distraction. The pharmacist explained there had been no dispensing errors reaching members of the public since the previous inspection. This was an improvement from the previous inspection when errors and near misses were not recorded.

The pharmacy had a complaints procedure. Sometimes people complained when their prescriptions were not ready as they expected. The pharmacist explained that the GP practice was under pressure and was sometimes behind, therefore prescriptions were late arriving at the pharmacy. The pharmacy team explained the process to people, including the time it took at the pharmacy to dispense medicines and sometimes order them. Team members made every effort to locate prescriptions that were already in the pharmacy and dispensed them as soon as possible for people.

The pharmacy had an indemnity insurance certificate, expiring 30 April 20. It displayed the responsible pharmacist notice and had a Responsible Pharmacist log. But some pharmacists had not recorded 'signing out' times which were part of the legal requirement for this record. The pharmacy had private prescription records, including records of emergency supplies and veterinary prescriptions, but no records had been made since July 2019 i.e. seven months ago. Around 30 prescriptions that should have been recorded were observed. This was also a legal requirement. The pharmacy did not have unlicensed specials records, the pharmacist explained that he seldom supplied these. The pharmacy had controlled drugs (CD) registers with running balances maintained and audited. Some were done monthly, some three monthly and methadone solutions weekly. But discrepancies observed in the methadone register were not investigated.

The pharmacy recorded the supply of CD medicines when they were dispensed, rather than when they left the premises. So the running balances in the registers did not match the quantity in stock. This was not in line with legislation which required entries to be made when medicines were supplied. Some entries stated ‘registrar’ rather than a named prescriber, again not in line with legislation, which required details of the prescriber. The pharmacy kept a register for patient returned CD medicines. But some entries were incorrect, in that they were not medicines returned by people.

Pharmacy team members were aware of the need for confidentiality. They had all read the relevent SOP, which they had not done at the time of the last inspection. They segregated confidential waste for secure destruction. No person identifiable information was visible to the public. Team members had also read the SOP related to safeguarding. They knew how to raise a concern locally and had access to contact details and processes. The pharmacist explained a recent situation where the pharmacy had concern for a patient so contacted the GP practice and other relevant agencies. The other agencies responded and addressed the concern. They gave the pharmacy advice for dealing with future concerns.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough qualified or team members in training to provide its services. Trainee team members have access to training material to ensure that they have the skills they need. And the pharmacy gives them time to do this training during the working day. The pharmacy team members discuss some of the mistakes they make to improve their learning. And to help them avoid making the same mistakes again.

Inspector's evidence

The pharmacy had the following staff: one full-time pharmacist manager (superintendent), one full-time and one part-time (20 hours per week) trained dispenser, one full-time trainee medicines counter/dispensing assistant, one Saturday only dispenser/medicines counter assistant, one trainee dispensing/medicines counter assistant on zero hours and a part-time delivery driver. The pharmacy had electronic copies of some certificates of qualification. Typically, there were three team members and the pharmacist working at most times, as there was during the inspection. Some days the pharmacy had four team members working, and assembled compliance packs on these days. Team members were able to manage the workload. The pharmacy reviewed staffing levels last week. The pharmacist explained that part time and ‘zero hours’ team members could work to cover absence and increase resource during busy times. This was an improvement from the previous inspection when there were not enough team members. And they had not received training for their roles.

The pharmacy provided learning time during the working day for team members undertaking accredited courses. A trainee team member described asking the pharmacist and colleagues for help and advice. If other dispensers were unable to help, all team members including the pharmacist discussed the question. The pharmacy did not have any ongoing training or development. The pharmacist explained that the focus was supporting trainees to complete their courses currently. Team members asked appropriate questions when supplying medicines over-the-counter and referred to the pharmacist when required. They demonstrated 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 discussed these at the time and the pharmacist provided information to educate team members. But they did not review these or introduce strategies to minimise repeat incidents. They had an open environment in the pharmacy where they could share and discuss these. There were no examples of team members raising concerns on making suggestions. But they gave appropriate responses to scenarios posed. The pharmacy did not set targets.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are safe and mostly clean. They are suitable for the pharmacy's services. The pharmacy team members use a private room and a discreet area for some conversations with people. Other people cannot overhear these conversations. The pharmacy is secure when closed.

Inspector's evidence

These were average-sized premises incorporating a retail area, dispensary and large basement. The basement included a room used for the management of multi-compartment compliance packs and instalment prescriptions, storage space and staff facilities. Most areas of the premises were clean and hygienic. But some areas of the basement were very untidy and dirty. This did not have an impact on people using the pharmacy. The pharmacy was in the early stages of planning a refit. It was hoped that would address these issues. The pharmacy had had a blocked sewage pipe a few weeks previously. It had arranged repair, and this was ongoing. 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 desk, chairs, sink and computer which was clean and tidy, and the door closed providing privacy. The pharmacy also had a separate area for specialist services such as substance misuse supervision. Temperature and lighting were comfortable.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy helps people to ensure they can all access its services. The pharmacy team mostly provides its services safely and effectively. Team members give people information to help them use their medicines. And they provide additional advice to people taking higher-risk medicines. The pharmacy obtains medicines from reliable sources and mostly stores them properly. The pharmacy team knows what to do if medicines are not fit for purpose.

Inspector's evidence

The pharmacy was accessed by a level entrance and wide door. Team members helped people with the door if required. The pharmacy displayed a list of its services. It could provide large print labels on dispensed medicines to help people with impaired vision. The pharmacy provided a delivery service and people signed to acknowledge receipt of their medicines.

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. This was an improvement since the previous inspection when baskets were not used. This posed a risk of people receiving the wrong medicine. Team members initialled dispensing labels to provide an audit trail of who had dispensed and checked all medicines. Again, this had been implemented since the last inspection.

Most of the pharmacy's dispensing was from different types of instalment prescriptions. The pharmacy managed multi-compartment compliance pack dispensing on a four-weekly cycle with four assembled at a time, about a week before the first pack was supplied. Some prescriptions were for eight or twelve weeks, so team members kept clear records to confirm when the first four weeks packs had been dispensed. When prescriptions were received the pharmacist checked them for completeness, he carried out a clinical assessment and ensured that the backing sheet on the computer records was correct. He attached a label to prescriptions confirming that he had checked them, how many weeks' supply the prescription was for (e.g. four, eight or 12) and start and finish dates. An experienced part-time dispenser usually assembled these packs. She took prescriptions to the basement after they had been checked, generated backing sheets then assembled the packs. The pharmacist sealed them when he checked them and both team members initialled backing sheets. The backing sheets did not have tablet descriptions on them. So it would be difficult to identify individual tablets in the event of a query or change in medication. The pharmacy kept the prescriptions, records of changes and other interventions in folders in the dispensary. It stored completed packs in individually labelled boxes on designated shelves. It stored packs for collection on shelves behind the dispensary, and those for delivery in the room where they were managed in the basement. And it stored packs containing controlled drugs in an approved controlled drug (CD) cabinet. At the time of inspection there were two packs dated for some weeks previously. The pharmacist undertook to confirm the reason but thought the patient was in hospital. The pharmacy supplied patient information leaflets with the first pack of each prescription.

The pharmacy supplied a lot of other medicines by instalment. A team member, usually the full-time dispenser, assembled instalment prescriptions in their entirety and the pharmacist checked the instalments. The dispenser bagged and labelled instalments for individual patients and placed them in boxes labelled by date of supply. These were stored in the basement and a team member took that

day's instalments to the dispensary each morning. When the pharmacy received prescriptions for methadone the pharmacist used pink or green highlighter pens to clearly mark which were for sugar free and which were for original solutions. A team member entered the data onto the patient medication record and printed all labels for the duration of the prescription. The pharmacy kept methadone labels with dispensed tablets for people supplied with both. This ensured that team members gave people all the medication that they should receive. The pharmacy denatured methadone 'dregs' in bottles using bleach then poured this into cat litter for destruction, rather than denaturing kits designed for this purpose. All team members supervised methadone consumption at the hatch. They asked people their date of birth to confirm identity. But a team member was observed to walk away from the hatch after handing the supervised dose of methadone to a patient. She did not actually supervise consumption, which was not in line with the SOP. People were given a drink of water following their medication only if they requested it. At the previous inspection team members did not ask people for any identification, meaning the wrong medicine could be supplied.

A pharmacist undertook clinical checks and provided appropriate advice and counselling to people receiving high-risk medicines including valproate, methotrexate, lithium, and warfarin. The pharmacy had put the guidance from the valproate pregnancy prevention programme in place. It had undertaken a search for people in the 'at-risk' group and the pharmacist had counselled them appropriately. 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, and chlamydia treatment. The pharmacy empowered team members to deliver the minor ailments service (eMAS) within their competence. 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 part-time dispenser mostly delivered the smoking cessation service. There were only a few people currently accessing this and they were all receiving nicotine replacement therapy.

The pharmacy obtained medicines from licensed wholesalers such as Alliance and AAH. It did not yet comply with the requirements of the Falsified Medicines Directive (FMD). The pharmacy stored most medicines in original packaging on shelves, in drawers and in cupboards. But it had a few loose strips and part strips of tablets on shelves in the dispensary in the basement. And it had loose tablets in bottles that were not appropriately labelled e.g. they had no batch number and expiry date. These included temazepam and buprenorphine which required to be stored securely in an approved CD cabinet. The pharmacy also had a complete pack of temazepam on the same shelf. A team member moved these immediately when this was identified and placed them in a CD cabinet. The pharmacy stored items requiring cold storage in a fridge and team members monitored minimum and maximum temperatures and 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 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 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, crown stamped measures used for methadone, and ISO marked measures for water. It also had a hand pump for methadone. Team members cleaned it and poured test volumes each time it was used. The pharmacy team kept clean tablet and capsule counters in the dispensary and kept a separate marked one for cytotoxic tablets.

The pharmacy stored paper records in the dispensary and basement 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 never left 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.