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: 18/08/2020

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. The 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 team members follow written processes to help deliver services safely. The pharmacy keeps the records that it is required to by law. Team members record mistakes to learn from them but do not review these so may be missing some learning opportunities. They keep people's private information safe and know how to help protect vulnerable people.

Inspector's evidence

The inspection was carried out over two days as key people were not present on the first day. Team members had ownership of certain activities and the regular pharmacist and dispenser who knew how controlled drugs were managed were not present on the first date. So sufficient evidence could not be obtained. The pharmacy had put strategies in place to keep people safe from infection during the COVID-19 pandemic. It had screens up at the medicines counter, hand sanitiser at the premises entrance, and face masks to offer to people who entered the pharmacy not wearing one. Recently the pharmacy had created a small porch-style room at the entrance for the supply and supervision of methadone. This minimised footfall into the retail area and the consultation room with infection control in mind. It enabled the pharmacist to supervise supplies and self-administration. People's confidentiality could be compromised as team members unlocked an inner door to enable other people into the retail area and to approach the medicines' counter. When asked, team members stated that there had been no complaints or concerns raised about this arrangement. People were observed queuing outside during the inspection and before the pharmacy opened. Most people coming to the pharmacy wore face coverings. Team members were not wearing masks on either day but put them on when asked to by the inspector. The dispensary was small so they were not able to socially distance. A dispensing area in the basement was larger and social distancing was possible there. Team members cleaned dispensing surfaces once a day, and the entrance area several times a day. The pharmacy manager had carried out a personal risk assessment by phone with a team member who had recently returned from shielding. He was working in the basement with minimal contact with colleagues and no contact with other people.

The pharmacy had standard operating procedures (SOPs) for most activities and team members mostly followed them. Pharmacy team members had read them, and the pharmacy kept records of this. But t eam members were not familiar with the contents of some of them e.g. management of controlled drugs. And they did not monitor and record fridge temperatures as the SOP required during the regular pharmacist's absence. Or follow the requirements of the responsible pharmacist SOPs in that they were carrying out activities without a responsible pharmacist signed in. They were not clear about which activities could not be carried out without a responsible pharmacist. And as noted below, a team member signed the pharmacist in to the electronic responsible pharmacist record to enable some activities requiring access to the computerised labelling system to be carried out. Following the inspection the regular pharmacist (superintendent pharmacist) provided assurance that this was a 'one-off' situation arising from misunderstanding of how the reduced patient-facing hours during the pandemic were managed. He explained that all team members and relief pharmacists were now briefed and appropriately trained. And they were following the SOP regarding monitoring fridge temperatures (see below, Principle four). The 'management of controlled drugs' SOP did not refer to frequency of stock audits. The pharmacy superintendent reviewed SOPs every two years and signed them off. The pharmacy managed dispensing, its main activity, appropriately, with coloured baskets used to

differentiate between different prescription types and separate people's medication.

Team members used near miss logs to record dispensing errors that were identified in the pharmacy, known as near-miss errors. They had recently started using a computerised system and had not yet reviewed these. The inspector noted that wrong 'form' was a common error. A trainee dispenser agreed and explained this was related to inexperience and unfamiliarity with product ranges. Usually the action taken was recorded as 'corrected'. The inspector advised on careful reading of the complete prescription and recording more meaningful actions.

The pharmacy had indemnity insurance, expiring 30 June 2021. The superintendent pharmacist (SI) provided a scanned image of the certificate following the inspection. in the previous visit on 18 August 2020, the pharmacy displayed the wrong responsible pharmacist notice. During this inspection the locum pharmacist who was working and had worked the previous day had not displayed his notice. The pharmacy was displaying the superintendent pharmacist's (SI's) notice. He had worked the days prior to that. The responsible pharmacist log was not kept accurately. On the day of the second inspection the locum pharmacist told the inspector he arrived at the pharmacy at 9.55 am but the RP log recorded his start time as 9.05 am. A team member had used his registration number to log him in to enable her to process prescriptions. The pharmacist was not aware that this had happened. He explained that the SI had told him the pharmacy opened at 10am. The accuracy of other entries was not known. For at least a month all log-in entries were after 9am, sometimes as late as 9.30am, despite the NHS contract starting each day at 9am. During the pandemic the NHS had allowed pharmacies to close for an hour in the morning to allow work to be undertaken without interruption, but RP Regulations still applied. Team members stated that the regular pharmacist was always in 'at the crack of dawn'. Legislation required the record to be accurate and reflect who the responsible pharmacist was at any given date and time. The responsible pharmacist was required to make the record personally and contemporaneously. Following the inspection the SI assured the inspector that this record keeping was related to relief pharmacists' misunderstanding of the pharmacy's hours of opening. As noted above this had now been addressed through briefing and training. Controlled drug and private prescription records including records of emergency supplies and veterinary prescriptions had been changed from paper to electronic versions a few months previously. This had contributed to much improved record keeping in these areas. A team member and the pharmacist carried out controlled drug running balance audits approximately monthly although some intervals of checking were observed to be longer. As noted above the SOP did not include this. The electronic record was set up with a reminder every 28 days. Balances randomly checked were correct. A CD destruction register for patient returned medicines was observed with the last entry and destruction in March 2020 (five months previously). No patient returned controlled drugs were observed. The pharmacy backed up electronic patient medication records (PMR) each night to avoid data being lost.

Pharmacy team members were aware of the need for confidentiality and had some understanding of safeguarding. These topics had been covered in their formal training. They segregated confidential waste for secure destruction and removed people's names from labels on bottles for destruction. No person identifiable information was visible to the public. They knew how to raise a safeguarding concern locally and had access to contact details and processes.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough team members either qualified or undertaking appropriate training to provide its services. The pharmacy gives them time during the working day to do this training. But it does not provide any on-going training or development which means team members may find it difficult to keep up to date with the skills and knowledge they need. Team members can make decisions relevant to their role.

Inspector's evidence

The pharmacy had the following staff: one full-time pharmacist manager, two full-time and two part-time dispensers, one Saturday only dispenser and a part-time delivery driver. One full-time and one part-time team member were still undertaking accredited training for dispensing and medicines' counter qualifications. The others were trained for both. Typically, there were three team members and a pharmacist working at most times. Team members were able to manage the workload. The inspection was carried out over two days and there was a different locum pharmacist each day. One was an employee of the parent company.

The pharmacy provided learning time during the working day for team members undertaking accredited courses. But the pharmacy did not provide time or material for ongoing training or development. This had contributed to an un-met standard in June 2019. Team members were observed going about their tasks in a systematic and professional manner. Experienced dispensers had ownership of processes such as the management and dispensing of instalment prescriptions and multi-compartment compliance packs. They worked to ensure these tasks were completed in advance of planned absence. A dispenser explained that they could deputise for each other although they may be a 'little rusty' to begin with. They did not routinely undertake each other's activities. Team members were observed taking phone calls and discussing prescriptions with prescribers. They provided information clearly and accurate and made appropriate decisions.

Pharmacy team members understood the importance of reporting mistakes and were comfortable owning up to their own. As noted above they kept records of near-miss errors. The dispensers working in the basement area on instalment and multi-compartment compliance pack dispensing explained that they made very few mistakes because they had time and space to work in a methodical manner. The team had occasional informal team meetings at the start of the day and discussed a variety of topics including the new Pharmacy First service. There were no examples discussed about making suggestions or raising concerns although this had been discussed satisfactorily at the inspection in February 2020. 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 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 instalment and multi-compartment compliance pack prescriptions, storage space and staff facilities. Some areas of the basement were damp, dirty and untidy, as noted in the previous inspection report in February 2020. The dispensing room was clean and tidy and had a de-humidifier running. The basement had been flooded the previous week. Team members had arranged for disposal of equipment and other items damaged and destroyed. Other areas of the premises were basically clean, hygienic and well maintained. Team members cleaned dispensing benches once a day, which was less often than some pharmacies during the pandemic. 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. This room would benefit from being tidied. The door closed providing privacy. The team was seldom using the room currently as it was difficult to maintain an acceptable distance from people. The pharmacy had recently installed a 'porch' area just inside the door, with a screen and hatch to the retail area for delivery of substance misuse services. A door led into the retail area and medicine counter for people accessing these areas.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy helps people to access its services, including having telephone consultations with people. It provides its services safely. The pharmacy obtains medicines from reliable sources and stores them appropriately.

Inspector's evidence

The pharmacy's usual hours were 9am to 5.30pm but it was still making use of the NHS allowed closures so opening at 10am, closing between 1pm and 2pm, then closing at 5.00pm. As noted above the inspector visited the pharmacy on two consecutive days. On the first day the pharmacy did not open until 10.10am. The following day the inspector called the pharmacy at 9.10am to arrange access before the pharmacy was open to the public at 10am. The phone voice message gave the hours of opening as 9am to 5.30pm. The inspector asked to speak to the pharmacist, but a team member stated that he was not there. When the inspector later discussed times with the locum pharmacist, he stated that he had arrived at the pharmacy at 9.55am, having been told by the superintendent pharmacist (SI) that the pharmacy opened at 10am. The (SI) had assured the inspector the pharmacy was accessible during the normal opening hours via telephone, email and the new Pharmacy Near Me service. Where necessary, he explained patients had been admitted during the restricted hours. The responsible pharmacist log showed that for at least the month of August there was not a pharmacist logged in until after 9am. And on the day of the first inspection visit (18 August 2020) the pharmacist logged off at 5.10pm. So, pharmacy services were not always available to people during the advertised hours. Following the inspection the SI pharmacist made immediate improvements to this. He contacted NHS Lothian to confirm that closure as described was still permitted within the NHS contract during the pandemic. He then changed the voice message on the phone to explain how the pharmacy team could be contacted out of the hours that the pharmacy was open to people. This was confirmed by the inspector. And he had made arrangements to have the website updated. The pharmacy now had a more professional looking notice on the door describing the hours of opening and giving the pharmacy phone number, email address and access to the NHS NearMe video consultation tool. This ensured that pharmacy services were available throughout the contracted hours, while still giving the pharmacy team time to catch up with any back-log of dispensing and clean surfaces in the pharmacy. The pharmacy listed its services and had leaflets available on a variety of topics. It could provide large print labels for people with impaired vision. The pharmacy provided a delivery service and people usually signed to acknowledge receipt of their medicines but were not being asked to do so during the pandemic. There had been an increase in deliveries due to people self-isolating and shielding.

Pharmacy team members followed a logical and methodical workflow for dispensing. They used coloured baskets to differentiate between different prescription types and to separate people's medicines and prescriptions. The pharmacy did not receive many walk-in prescriptions which helped the team to manage the workload. Most prescriptions were collected from surgeries and many of these were for different types of instalment dispensing. When they were received an experienced dispenser or the pharmacist went through them and separated prescriptions into different categories. A trainee dispenser worked through the straightforward ones with more experienced team members processing others. Different team members had ownership for managing instalment prescriptions, methadone prescriptions and those for multi-compartment compliance packs. Team members initialled dispensing labels to provide an audit trail of who had dispensed and checked medicines, but not for methadone.

This had contributed to the pharmacy not meeting a standard in June 2019. The pharmacy usually assembled owings later the same day or the following day. Some dispensed medicines had been on the retrieval shelves for supply to people for a long time, with no investigation or contact made to the people. This could mean that people did not have medicines they needed. Examples included inhalers from 14 May 2020, antibiotics (doxycycline) from 20 March 2020 and heart medication (nifedipine) from 27 March 2020. Team members thought some or all of these medicines may have been ordered excessively at the start of the pandemic and therefore not actually be required.

The pharmacy managed multi-compartment compliance pack dispensing on a four-weekly cycle with four assembled at a time. The process was basically the same as at the last inspection when it was satisfactory. The pharmacy did not put tablet descriptions on the backing sheets. This was highlighted at the previous inspection, but team members had not seen the report. The team member responsible for this process stated that she would make that change. Following the inspection the SI pharmacist confirmed that this was in progress. The team member supplied patient information leaflets with the first pack of each prescription. She explained that due to time lost the previous week when the pharmacy had flooded, she was behind with her workload. She was assembling packs for supply this week, when typically, she would be working a week ahead. The following day the locum pharmacist was checking packs for supply that day. He was under pressure to be able to give them to the delivery driver at a certain time. The pharmacy supplied a variety of other medicines by instalment. A team member assembled these in their entirety when prescriptions were received in the same way as seen at the last inspection in February 2020. The team also assembled methadone instalments in the same way as before, but as noted above not signing dispensing labels to provide an audit trail.

A pharmacist undertook clinical checks and provided appropriate advice and counselling to people receiving high-risk medicines including valproate, methotrexate, lithium, and warfarin. He 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. It had previously undertaken a search for people in the 'at-risk' group. The pharmacist had counselled them appropriately and checked that they were on a pregnancy-prevention programme. 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 NHS 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 offered the NHS smoking cessation service, with many consultations undertaken by the experienced part-time dispenser. But demand for the service had decreased during the pandemic and there was currently only one person accessing it. Carbon monoxide readings were not being taken for infection control reasons. The pharmacist sometimes measured blood pressure on request or if he identified a clinical need but similarly was not doing this now.

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 medicines in original packaging on shelves, in drawers and in cupboards. It stored items requiring cold storage in a fridge but the team did not record fridge temperatures. A team member had recently moved stock into the fridge in the dispensary. She had moved it from another area a few days before. She had waited for the temperature to settle before transferring the stock. During the inspection the current temperature was within the accepted range of 2C - 8C. But minimum and maximum temperatures were checked and found to be 3.5C – 14.9C. Team members thought that the reason was

that the thermometer may not have been re-set when the fridge was moved to this location. The inspector advised the pharmacist and team that they should take advice from 'Medicines Information' or manufacturers, then take appropriate action to ensure the fridge contents were still fit for purpose. Following the inspection the SI pharmacist provided evidence that he had been recording fridge temperatures daily before his holidays but team members had not done this in his absence. They had now been trained and were recording daily. The SI had taken advice from a consultant in diabetes in the local hospital about the consequences of the possibility that two types of insulin may not have been refrigerated for a short time. The consultant assured him that the integrity of the insulin would not be affected and it could be stored out of a fridge for up to 28 days. So the pharmacy team members were explaining to any people supplied with this insulin that they should keep it refrigerated. 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. And it looks after it 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 used a de-humidifier to try and keep the basement dry. It had been destroyed in the recent flood, so a replacement was ordered immediately. It was observed to be in use following receipt on the day of the second inspection visit.

The pharmacy had face masks and hand sanitiser for team members to use as required. They kept a carbon monoxide monitor maintained by the health board and a blood pressure meter in the consultation room. Due to the pandemic they were not currently using this equipment. The pharmacy had crown stamped and ISO marked measures by the sink in the dispensary, and team members used separate marked ones for methadone. The pharmacy had a hand pump available for methadone use and team members poured test volumes before use to ensure it was measuring accurately. They cleaned it after use. The pharmacy team kept clean tablet and capsule counters in the dispensary and kept a separate marked one for cytotoxic tablets.

The pharmacy kept 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 did not leave them unattended unless they were locked. But team members were able to access the responsible pharmacist record and log-on. This meant that sometimes there was no responsible pharmacist, but the records showed that there was.

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.