General
Pharmaceutical
Council

Registered pharmacy inspection report

Pharmacy Name: Ratho Pharmacy, 64 North Street, Ratho, NEWBRIDGE, Midlothian, EH28 8RR

Pharmacy reference: 1042769

Type of pharmacy: Community

Date of inspection: 13/05/2019

Pharmacy context

This is a community pharmacy set in a row of shops in a village. The area is growing due to new homes being built. 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 mullti-compartmental compliance packs.

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 manage all risks. It does not have standard operating procedures. This means mistakes could happen.
		1.2	Standard not met	The pharmacy does not record or review mistakes. So, it is missing an opportunity to learn from these and avoid the same mistakes happening again.
		1.6	Standard not met	Pharmacists do not complete the responsible pharmacist record accurately. This is a legal need. The inaccurate entries could shift responsibility to the wrong person.
		1.7	Standard not met	The pharmacy does not always protect people's personal information.
2. Staff	Standards not all met	2.2	Standard not met	The pharmacy does not ensure that all team members are suitably trained and qualified for their role.
		2.4	Standard not met	The pharmacy does not learn from previous feedback such as inspection reports. It does not share information and incidents within the wider organisation to learn and improve services.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy does not have potable running water. The only sink is in the toilet area. Pharmacy team members wash cups and medicine measures in this area and then store them here.
		3.2	Standard not met	The premises does not protect people's information. Team members have private conversations with people on the shop floor, and in an area where personal information is visible.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	There is a risk that services may be unsafe as there are no standard operating procedures in place. The pharmacy team members do not always give people the extra information needed with some

Principle	Principle finding	Exception standard reference	Notable practice	Why
				medicines.
		4.3	Standard not met	The pharmacy does not store all medicines properly. And it does not routinely check expiry dates. So, it could supply out of date medicines.
5. Equipment and facilities	Standards not all met	5.1	Standard not met	The pharmacy does not have equipment to destroy confidential waste. So, people's personal information could be seen within general waste.

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not follow documented processes so there is a risk of mistakes. Mistakes are not recorded so the team are missing learning opportunities. The pharmacy keeps most records as it must by law. But it does not keep accurate records of the responsible pharmacists. The pharmacy does not always keep people's information safe. Team members do not always know how to protect vulnerable people.

Inspector's evidence

The pharmacy did not have any Standard Operating Procedures (SOPs) in place. Pharmacy team members present during inspection had not read or signed SOPs in this pharmacy. There was a folder containing archived standard operating procedures from 2014 (five years previously) and under the previous ownership . The dispenser working at the time had not seen these. A dispenser present during the inspection described processes that were followed for the various activities including dispensing different types of prescriptions.

Dispensing, a high-risk activity, was observed to be smooth with baskets used to separate patients' medicines and prescriptions. There was an audit trail in place for dispensed medicines in the form of dispensed and checked by signatures on labels. The pharmacy did not have a business continuity plan in place but did have phone numbers for a few trade companies.

The dispenser stated that near miss logs were available, but pharmacy team members could not find them. They did not review incidents or errors. Team members present were not aware of recent errors reaching people.

Staff members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist.

The pharmacy did not have a complaints procedure. Team members could not describe any complaints.

An indemnity insurance certificate was displayed expiring February 2020.

The following records were maintained in compliance with relevant legislation: responsible pharmacist notice was displayed; responsible pharmacist log. But this record was incomplete as pharmacists had not recorded the time their responsibility ended. An example was observed of a pharmacist starting at 9.16am. The pharmacist the previous day had not recorded her end time. The pharmacy kept private prescription records including records of emergency supplies and veterinary prescriptions; unlicensed specials records and controlled drugs registers, with running balances maintained. The running balances had not been audited for two months. Records of patient returned controlled drugs were kept. The electronic patient medication record (PMR) was backed up daily.

Staff members were aware of the need for confidentiality. As the pharmacy did not have a consultation room, the back-shop area was used for some consultations. It was accessed through the dispensary. Managing confidentiality was challenging. Dispensed medicines waiting to be supplied, including multi-compartmental medicines packs were stored in this area with names and addresses visible. Confidential

waste was torn by hand and placed with general waste. There had been a shredder in use, but this had broken a few months previously and not replaced. The owner had been told.

There was awareness of safeguarding as the pharmacist had undertaken training and the dispenser had previous experience from another workplace. There was no policy in place and no local contact information was observed. The pharmacist working at the time of inspection did not normally work in this area, so did not have previous knowledge of local contacts. The dispenser described a situation where a patient was not managing her medicines. She had contacted the GP practice and arranged for the patient to be assessed. Medicines were now being supplied in original packs with medicines administration records (MAR) charts. The pharmacist was PVG registered although the pharmacy owner had not asked for the registration number.

Principle 2 - Staffing Standards not all met

Summary findings

The pharmacy has enough trained or team members in-training to provide its services. But the trainees do not have time set aside to complete their courses. And the pharmacy team 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. The pharmacy does not learn from previous experience or incidents elsewhere.

Inspector's evidence

Staff numbers in the pharmacy: one ‘full-time equivalent’ pharmacist achieved by a variety of locum pharmacists, three part-time dispensers, one was undertaking training for dispensing and medicines counter tasks and worked one and a half days in this pharmacy. She worked other days in another branch in the company. Another dispenser, who worked three afternoons per week was not medicines counter trained. The third dispenser was trained as a medicines counter and dispensary assistant. Typically, there was one staff member and a pharmacist working. Three afternoons per week there were two dispensers. Tasks such as management of multi-compartmental medicines packs were undertaken when there were two staff members present. There was scope to cover absence as part-time team members were often able to work increased hours. This was the case during the inspection.

The pharmacy did not allocate training time for team members. The dispenser present at the time of inspection had worked in this pharmacy for around three years, and another pharmacy in the organisation for around two years. She had not yet completed her joint medicines counter and dispensary assistant course. ‘Counter excellence’ booklets were read on-the-job as they were received into the pharmacy. This was ad-hoc and there was no routine training or development in place. Team members had not had development meetings.

Team members were observed to manage the workload as the pharmacy was quiet during the inspection. They were observed going about their tasks in a systematic and professional manner. They had a friendly and professional manner when speaking to people. Appropriate questions were asked when selling over-the-counter medicines. A dispenser displayed awareness of items of abuse.

The dispenser described on-the-job sharing of information with team members although this was not observed due to the few staff members present during inspection. There was no evidence of information shared across the company. The pharmacy had not made sustained improvements following the previous inspection several years before. (It was under different ownership at that time). People using the 'consultation area' could see other people's information on dispensed medicines. The pharmacy had made changes at the time to address this. But this had not been sustained. And the same concern was seen at this inspection. Targets for services were not set.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy is safe and clean but not suitable for all its services. It is not suitable for private consultations. It does not always protect people's information. The pharmacy does not have potable running water. The pharmacy is secure when closed.

Inspector's evidence

These were average sized premises with a small but adequate dispensary for the workload. The pharmacy did not have a consultation room but used a back-shop area if required. It was accessed via the dispensary. The dispenser present during inspection explained that consultations using this area were infrequent. Most consultations took place on the shop floor in a discreet manner but this was not observed. Dispensed medicines waiting to be supplied including multi-compartmental medicines packs were stored in this back-shop area. Personal information was visible.

The dispensary did not have a sink, and the only staff facility was a toilet. The sink in the toilet area had cold and hot running water, soap and hand towels. It was used for washing staff cups and dispensing measures. There was a lead water tank, so water from this was not used for consumption. Team members used a 5L container of purified water for drinking and preparation of antibiotic suspensions. But they did not know how long it had been open.

People were generally not able to see activities being undertaken in the dispensary. They could see dispensing activities if they were going to the back-shop area for a private consultation.

The premises were observed to be clean. Temperature and lighting were comfortable.

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

Summary findings

The pharmacy helps people to ensure they can use its services. There is a risk that the pharmacy does not provide safe services. This is due to lack of written procedures to guide team members. They give people information to help them use their medicines. But they do not always provide extra written information to help people to take their medicines safely. The pharmacy gets medicines from reliable sources. But it does not store these all properly. There is a risk that the pharmacy supplies medicines that are out of date.

Inspector's evidence

There were steps into the pharmacy and assistance was given if required. Sometimes team members did not see people entering the pharmacy as they were in the dispensary. There was a handrail on the premises waiting to be installed, to assist people with poor mobility. People often phoned the pharmacy for advice, or to request a prescription. Pharmacy team members delivered medicines to some people who had difficulty accessing the pharmacy. They offered to help people any way they could while in the pharmacy e.g. locating items to purchase. The pharmacy could provide large print labels on dispensed medicines for people with impaired vision. The pharmacy had a small range of leaflets on different topics.

Dispensing work flow was observed to be smooth and logical. The pharmacist usually labelled the prescriptions. This enabled her to carry out a clinical check. Each patient's prescriptions were placed with labels in a basket and dispensed on another bench by a dispenser. The pharmacist undertook the final accuracy check on a designated area of the same bench. Occasionally pharmacists dispensed, and this was observed. The pharmacist asked the dispenser to undertake a final accuracy check. Dispensing audit trails were in place in terms of initials on dispensing labels of personnel who had dispensed and checked medicines. Owings were usually assembled later the same day or the following day.

There was a delivery service. Dispensers delivered medicines to patients in the village during their lunch break. They delivered to other villages nearby on Thursdays, using their own cars. The dispenser present during inspection did not undertake this task and did not know if her colleagues' cars were insured for business use.

Multi-compartmental medicines packs were managed on a four-weekly cycle with four assembled at a time. When prescriptions were received, the pharmacist checked them for accuracy and completeness. After assembly, reorder forms were attached to the third pack to ensure that prescriptions were ordered and received in adequate time for the next cycle. The pharmacy kept records of changes chronologically on patient records sheets. They did not keep records of prescribers who had made changes. Backing sheets had tablet descriptions and date of commencement for that pack on them. But they were attached to packs loosely, meaning they could become detached. The spine of each pack was labelled with patient name and date of supply. Completed packs with additional medication were stored logically and tidily. As noted above, this information was visible to people having private consultations.

The locum pharmacist present during the inspection was aware of the pregnancy prevention program but as she did not regularly work in the pharmacy she did not know how it applied to people here. The

dispenser was not aware of it. She was aware of labelling on manufacturers' packaging but not any support material. She did not know if a search for relevant people had been undertaken or advice given. The dispenser knew that some people were on high-risk medicines such as methotrexate, but she did not know how pharmacists advised people. The non-steroidal anti-inflammatory drug (NSAID) care bundle guidance was on the dispensary wall, but the dispenser explained there was no written material available for people being supplied with these medicines. 'Sick day rules' information was available.

NHS services followed the service specifications and current patient group directions (PGDs) were observed for pharmacy first and emergency hormonal contraception only. The locum pharmacist at the time of inspection did not usually work in this health board area and had not signed PGDs for the area. This meant she would be unable to offer any of the services provided under PGD. Staff members were empowered to deliver the minor ailments service (eMAS) within their competence.

Invoices were observed from licensed suppliers such as AAH and Ethigen. The pharmacy did not comply with the requirements of the Falsified Medicines Directive (FMD). Team members were aware of the basic requirements. The hardware was in place but not yet functional.

Records of date checking and stock rotation were observed, but out of date. The most recent entry was nine months previously. On inspection, several items were found to be short dated e.g. expiring in the current month or the following months. Most medicines were stored in original packaging on shelves. But the inspector observed and removed several bottles of loose tabs not correctly labelled. Team members did not know when they had been removed from the original packaging. 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.

Controlled drugs (CDs) were stored in a safe that had previously had an exemption certificate. Police Scotland no longer issue these certificates. The safe was observed to be congested and there was no space for any additional items.

Pharmacy (P) medicines were protected from self-selection. Sale of P medicines was as per sale of medicines protocol. Effective advice and counselling were observed.

Team members present during the inspection did not know how MHRA recalls and alerts were managed, and no records were observed. Items received damaged or faulty were returned to suppliers as soon as possible.

Principle 5 - Equipment and facilities **Standards not all met**

Summary findings

The pharmacy has most of the equipment it needs for delivery of its services. Some equipment needed to be cleaned. The pharmacy does not always promptly replace damaged equipment.

Inspector's evidence

Texts available in the pharmacy included current editions of the British National Formulary (BNF) and BNF for Children. There was IT access allowing online resources to be used.

There was a carbon monoxide monitor, maintained by the health board, available for people accessing the smoking cessation service. Crown stamped measures were available and separate marked ones were used for methadone. The pharmacy kept these on a shelf with staff cups, close to the toilet sink (the only sink on the premises.)

Tablet and capsule counters were kept in a drawer in the dispensary and were observed to have tablet residue on them. As methotrexate tablets were supplied in blister packaging there was no longer a separate counter kept for these.

Paper records were stored in the dispensary. The computer was never left unattended and was password protected. The screen was not visible to the public. The shredder for confidential waste which had broken several months previously had not been replaced. The pharmacy team members had notified the superintendent pharmacist. Care was taken to ensure phone conversations could not be overheard.

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.