General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Longniddry Pharmacy, 27 Links Road, LONGNIDDRY, East Lothian, EH32 0NH

Pharmacy reference: 1042029

Type of pharmacy: Community

Date of inspection: 09/05/2019

Pharmacy context

This is a community pharmacy set in a row of shops in a village. Many of the people who use the pharmacy are older people. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines, home and garden products and toiletries. It also supplies medicines in multi-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	There are unmet risks due to inadequate standard operating procedures (SOPs), staff issues, cramped dispensing area and dispensed medicines stored in baskets on the floor.
		1.2	Standard not met	Dispensing accuracy is not monitored and reviewed. The pharmacy is missing opportunities to learn from mistakes. This increases the risk of repeat incidents.
2. Staff	Standards not all met	2.1	Standard not met	Team members are not trained for their role, nor given time to complete training courses. And in some cases, not registered on courses for the role they are undertaking. The superintendent pharmacist does not have time to fulfil that role.
		2.2	Standard not met	There is no ongoing training and development. So team members may not have the skills to deliver the pharmacy's services.
		2.4	Standard not met	There is not a culture of learning within the organisation. The pharmacy have not addressed concerns raised at a previous inspection 2 years ago. They were briefly improved at the time, but this was not sustained.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards not all met	4.2	Standard not met	Pharmacy services are not managed safely and effectively for reasons noted above. This increases the risk the pharmacy may not deliver services safely.
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 some processes to ensure that they are safe. But some of these are out of date, and some are not complete. This means that some services might not be completely safe. The pharmacy does not follow a safe process for some dispensing of medicines. The pharmacy does not record mistakes. So, the team are missing learning opportunities. They could make the same mistake again. The pharmacy keeps all the records that it needs to by law and keeps people's information safe. Team members help to protect vulnerable people.

Inspector's evidence

Standard operating procedures (SOPs) were in place. They had been read and signed by relevant staff members. Templates were not all fully populated. They had been reviewed last year, and some had notes that they needed updated. The pharmacist (who was the superintendent (SI) pharmacist) explained that she was waiting for the requirements of the Falsified Medicines Directive to be implemented before updating them. Staff roles and responsibilities were recorded on individual SOPs. All aspects of the controlled drug (CD) SOP were the responsibility of pharmacist. She explained that only pharmacists handled controlled drugs. Not all controlled drug procedures were documented e.g. there was no process for receipt or storage.

Dispensing, a high-risk activity, was observed to take place in cramped conditions. Coloured baskets were used to separate each patient's medication. Red baskets were used to identify people who were waiting for their medicines. Baskets containing dispensed medicines waiting to be checked by the pharmacist were stored on the floor because there was no other available space on benches or shelves. This caused a risk as items could fall from shelves into them or they could be knocked over. There was an audit trail in place for dispensed medicines in the form of dispensed and checked by signatures on labels.

Near-miss logs were not kept. Errors which were identified during the final accuracy check were discussed at the time and corrected. But these were not recorded. This meant that reviews could not take place to identify any trends. The pharmacist described examples of moving items on shelves e.g. paroxetine and pantoprazole, as they came in similar packs. At the time of inspection, they were no longer separated but the packaging was different now. The strength of gabapentin capsules had been separated as the packaging was similar. Error reporting was in place, to record information regarding dispensing errors reaching patients. These were retained in the pharmacy. The most recent report observed was from around 18 months previously. The pharmacist explained that there had been no errors since then.

Staff members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist. They were clear regarding their roles. The trainee dispenser explained that she was not involved in handling controlled drugs.

There was a complaints procedure in place. The pharmacy team members could not think of any complaints. They gave examples of positive feedback. This included the pharmacy proactively delivering prescribed medicines to people on a temporary basis due to current health issues.

Indemnity insurance certificate was in place, expiring April 2020.

The following records were maintained in compliance with relevant legislation: responsible pharmacist notice was displayed; responsible pharmacist log; private prescription records including records of emergency supplies and veterinary prescriptions; unlicensed specials records and controlled drugs registers, with running balances maintained and regularly audited, approximately every 2 months. There was no SOP to cover this. Records of patient returned controlled drugs were kept and the electronic patient medication record (PMR) was backed up every night.

Staff members were aware of the need for confidentiality. Information had been read when they started employment. No person identifiable information was visible to the public. Confidential waste was segregated and taken for incineration. The owner of the pharmacy came weekly to collect this and burn it in her incinerator.

Team members had basic awareness of safeguarding, but they were not aware of any policy or training on the subject. The local process for raising concerns was on the dispensary wall. An example was described of contacting a patient's GP when the pharmacist had concern about cognitive function. A neighbour had also raised concern with the pharmacist. The pharmacist was PVG registered. The delivery driver brought a mult-icompartmental compliance pack back to the pharmacy during the inspection, to show compliance issues. The patient had told him that she had got confused. The pharmacist knew the patient well and was not concerned as only a few doses had been missed. She advised the patient to start afresh with the new pack. The pharmacist explained to the inspector that she would be monitoring the situation and contact the GP if necessary.

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

Summary findings

The pharmacy does not have enough trained and qualified staff to safely provide its services. Some team members are not undertaking training for qualifications or other skills. So, they may not be competent for the tasks they are undertaking. Trainees do not have time set aside to complete their courses. And 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. The pharmacy does not learn from previous experience and does not improve or develop services.

Inspector's evidence

Staff numbers working in the pharmacy: one full-time pharmacist (superintendent pharmacist), two part-time trainee dispensers, one part-time trainee medicines counter assistant, one day per week from another branch,one trainee medicines counter assistant, who worked alternate Saturday mornings only and one delivery driver.
A part-time medicines counter assistant, who worked three days per week was currently on maternity leave. Typically, there were three members of staff working at any time including the pharmacist.

Most staff members had worked in pharmacy for a few years, or longer. All were registered for training. But there was no time to do this training, e.g. one member of staff had worked in pharmacy for five years and had not completed dispensary training, and never undertaken medicines counter training. She regularly served on the medicines counter. A trainee medicines counter assistant from the other branch, had protected learning time there for her training. The pharmacist, who was also the superintendent pharmacist had no time to undertake activities associated with the superintendent role as she worked full-time as the responsible pharmacist.

Staff members were observed to manage the workload. The pharmacist undertook most tasks, as there was not always trained staff to delegate to. There was no ongoing training or development in place. At the time of inspection there were a lot of dispensed medicines waiting to be checked. These were in baskets on the floor as described above. Most dispensing was generated from prescriptions collected from the surgery, which enabled the pharmacist to manage the workload. The team members present during the inspection portrayed a professional image. They had a pleasant and friendly manner with people. They asked relevant questions and gave appropriate advice when selling over-the-counter medicines.

The team members present during inspection stated that they worked in an open environment where they could share information. They described understanding the importance of reporting mistakes and learning from these, although reporting of near misses was not happening. There was no sharing of incidents or opportunities for learning between the two branches in the organisation. The superintendent pharmacist did not have time to collate information or provide updates. There was no evidence of learning from the previous inspection two years ago. At that time concerns were raised regarding standard operating procedures, staff training, lack of learning from near misses, the cramped dispensing environment and medicines being stored on the floor. These issues were all observed during the current inspection.

The owner visited the pharmacy once per week, but the pharmacist was often busy with the general

day-to-day pharmacy activities, so this did not provide opportunity for meaningful conversations. There were no meetings either within the pharmacy or the wider organisation outside the working day. Information was shared between team members as they worked. The team members present new how to contact the owner should see had any concerns to raise.
Targets were not set.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is safe and clean. The area used for preparing medicines is small and cramped. This could lead to mistakes. The pharmacy is secure when closed.

Inspector's evidence

These were average sized pharmacy premises. There was a small medicines counter and very small dispensary. Space in the dispensary was challenging, and as noted elsewhere, medicines waiting to be checked were stored on the floor. The dispensary had an old-fashioned and ‘tired’ appearance. The retail area was spacious. Items for sale included general household and garden items, as well as medicines, toiletries and sundries.

There were staff toilet facilities. The sink in the staff toilet area and dispensary had hot and cold running water, soap, and clean hand towels. The premises were observed to be clean and hygienic.

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 and sink. The door closed providing privacy.

Lighting was appropriate. The pharmacy felt very cold, and the consultation room was colder.

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

Summary findings

The pharmacy team members help people to ensure that they can all use its services. The pharmacy mostly provides safe services. But lack of staff training and the way the pharmacy manages some processes increases the risk of mistakes. The pharmacy gets medicines from reliable sources and stores them properly.

Inspector's evidence

There was a step and heavy door at the entrance to the pharmacy. Team members helped people as they required. Services provided were displayed externally. Large print labels could be provided for people with impaired vision. Leaflets on a range of topics were available.

Dispensing work flow was observed to be methodical and logical. Sometimes the pharmacist labelled which enabled her to carry out a clinical check. If a dispenser was labelling and she noticed changes, she highlighted these to the pharmacist. The pharmacist then looked at the patient's medication record to inform her if any counselling or questioning was required. Dispensing and checking took place on the same small dispensing bench. As there was no space for medicines waiting to be checked these were stored in their baskets on the floor as noted elsewhere. 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. These were not set up as owings on the labelling system, but all labels printed. Stock was ordered, received and all items often dispensed before people came to collect prescriptions so there was no impact of this. However, if people came for their prescriptions before the owing had been dispensed, it was still not set up as an owing. This meant that if these labels were misplaced there was no record of items owed. The dispensing date was also then incorrect on the labels for the owing part. This also meant that there was no opportunity for monitoring or reviewing the level of owings or medicines involved.

There was a delivery service and signatures were obtained on receipt. Items requiring cold storage were taken immediately to people's addresses as most were quite local. The bag was labelled that the item required to be stored in the fridge. Usually medicines were handed directly to people, but occasionally they phoned to say they would not be in and asked that items were placed through the letterbox. The pharmacist checked that there were no children or animals in the property.

Multi-compartmental medicine packs were managed on a four-weekly cycle with four assembled at a time. Patient information leaflets (PILs) were supplied with the first pack of each prescription. Records were kept of changes and ordering and assembly dates. Instalment numbers were on backing sheets. Patients' names and dates of supply were on the spines of completed packs, and the day was highlighted. Prescriptions were ordered when the third pack was supplied. This usually give adequate time for prescriptions to be received, checked and assembled. At the time of inspection there were packs for the following day waiting to be checked by the pharmacist. The pharmacist explained that the reason for this was that the pharmacy had been closed on a public holiday, and she had worked in the other branch the previous week, with a locum pharmacist new to this pharmacy covering for her. There were a few prescriptions where medicines were supplied by instalment. One instalment at a time was assembled after the previous one was supplied.

Clinical checks were undertaken by a pharmacist and people receiving high-risk medicines including valproate, methotrexate, lithium, and warfarin were given appropriate advice and counselling. Written information and record books were provided if required. The valproate pregnancy prevention programme was in place. There were two people who were potentially affected by this. One had been counselled. The other one was more sensitive, but there were plans to change her onto other medication. The pharmacist was aware of the need to counsel if this did not happen. The non-steroidal anti-inflammatory drug (NSAID) care bundle had been implemented and written and verbal information was given to people supplied with these medicines over-the-counter, or on prescriptions. 'Sick day rules' were also discussed with people on certain medicines, so that they could manage their medicines when they were unwell.

NHS services followed the service specifications and patient group directions (PGDs) were in place for unscheduled care, pharmacy first, smoking cessation, emergency hormonal contraception, chloramphenicol ophthalmic products and chlamydia treatment. These were current, and the pharmacist had been trained and signed them. There were around 30 patients receiving medicines on chronic medication service (CMS) serial prescriptions. All were stable. Medicines were dispensed when people requested them, usually by phone. The pharmacist did not believe there were any compliance issues. Medicines were not synchronised at the start of the service delivery. People were being started on serial prescriptions by the practice pharmacist and registered when they came to the pharmacy. No pharmaceutical care issues were identified, but it was acknowledged that all people so far were on very straightforward medication. The pharmacist was involved in all requests for the minor ailments service. As the dispensary and medicines counter were very close together she could overhear all requests.

Invoices were observed from licensed suppliers such as Alliance.
The pharmacy did not comply with the requirements of the Falsified Medicines Directive (FMD). The hardware was in the pharmacy and software on the computer but not yet working. Records of date checking and stock rotation were not kept but the pharmacist said it was done every three months. All products inspected were in date.
Medicines were stored in original packaging on shelves and in drawers. 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 CD cabinet. Space was well used to segregate stock, dispensed items and obsolete items. Pharmacy (P) medicines were protected from self-selection. Sale of P medicines was as per sale of medicines protocol.

MHRA recalls and alerts were actioned on receipt and records kept. Patients were contacted following patient level recalls. 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. The pharmacy looks after this equipment to ensure it works.

Inspector's evidence

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

A carbon monoxide monitor maintained by the health board, was kept in the consultation room where it was used with patients accessing the smoking cessation service. Crown stamped measures were kept by the sink in the dispensary, and separate marked ones were used for methadone. Clean tablet and capsule counters were also kept in the dispensary, and a separate marked one was used for cytotoxic tablets.

Paper records were stored in the dispensary inaccessible to the public. The pharmacy did not have a shredder to destroy confidential waste, but the owner removed this and incinerated it. It was not known if this was secured in the vehicle or ever left unattended. Computers were never left unattended and were password protected. Screens were not visible to the public. 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.