General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Well, 100 Craigentinny Road, EDINBURGH,

Midlothian, EH7 6RN

Pharmacy reference: 1042642

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 suburb of a large city. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It also supplies medicines in multi-compartmental compliance packs. People of all age groups use the pharmacy.

Overall inspection outcome

✓ Standards met

Required Action: None

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 processes for most services to ensure that they are safe. They record some mistakes to learn from them. Team members are missing opportunities for learning and improving services because they do not record all mistakes. The pharmacy asks people for feedback to help make its services better. The pharmacy keeps most of the records that it needs to by law and keeps people's information safe. Pharmacy team members help to protect vulnerable people.

Inspector's evidence

Standard operating procedures (SOPs) were in place and followed for all activities and tasks. These were online and had been read by relevant staff members. Records of this were kept electronically. They were reviewed every two years and were signed off by the pharmacy superintendent. Staff roles and responsibilities were recorded on individual SOPs. The process for managing multi-compartmental compliance packs was not accurately followed. The area manager was aware. This had been risk assessed and the team had decided not to make changes currently due to changes in staffing over coming weeks.

Dispensing, a high-risk activity, was observed to be smooth with coloured baskets in use for dispensing to identify different prescription types e.g. people waiting. Retrieval shelves containing dispensed medicine waiting to be collected were observed to be very neat and ordered. This contributed to the accurate supply of medicines. There was an audit trail in place for dispensed medicines in the form of dispensed and checked by signatures on labels. Business continuity planning was in place to address maintenance issues or disruption to services. A list of phone numbers for maintenance issues or disruption to services was on the wall in the back-shop area.

Near-miss logs were kept and error reporting was in place. Only four had been reported the previous month. Team members acknowledged they were not using near miss logs consistently. Incidents were recorded electronically on Datix. The data was analysed, and feedback provided. The previous month it demonstrated that errors were only made two days per week – again staff acknowledged that this was not accurate. An error reaching a patient had involved an incorrect strength of medicine. It was being investigated, a report had been sent to head office and the team had apologised to the patient. And the patient had not suffered any harm. Items in similar packaging had been separated on shelves e.g. some tubes of cream.

Staff members could describe their roles and accurately explain which activities could not be undertaken in the absence of the pharmacist. All team members were competent to undertake all tasks.

There was a complaints procedure in place and the pharmacy used mystery shoppers periodically to provide feedback. Recent mystery shopper feedback had rated the pharmacy 100 per cent. A few years previously some processes in the pharmacy had not been managed well and patients had had to wait for prolonged periods for prescriptions. This had been resolved and waiting times were now much shorter. People had provided positive feedback that the service in the pharmacy was much improved. The heating on the premises had not been working during the winter and following a complaint to head

office from a member of the public, this had been repaired.

Indemnity insurance certificate was displayed expiring June 2019.

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. But, no private prescriptions had been recorded for the past six months. Some prescriptions were stapled into the register, some were correctly filed, and others were waiting in a 'pigeon hole' waiting to be recorded. Unlicensed specials records were maintained as were controlled drugs registers, with running balances maintained and regularly audited. Records of patient returned controlled drugs were kept. The electronic patient medication record (PMR) was backed up each night.

Staff members were aware of the need for confidentiality. They undertook annual training using the company's electronic training modules, E-expert. No person identifiable information was visible to the public. Confidential waste was segregated for secure destruction.

Similarly, all team members undertook annual safeguarding training. They were aware that local processes and contact details were available on the Community Pharmacy Scotland (CPS) website. The pharmacist was PVG registered. She undertook level II safeguarding training every two years. There was a chaperone policy in place. The delivery driver described how he knew the people he delivered medicines to, and he would tell the pharmacist if he was concerned that anyone looked unwell or confused.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy currently has enough qualified and experienced staff to safely provide its services. The pharmacy compares staff numbers and qualifications to how busy the pharmacy is. The pharmacy makes changes, but sometimes expertise is lost. Staff members have access to training material to ensure that they have the skills they need. The pharmacy gives them time to do this training. Team members can share information and raise concerns to keep the pharmacy safe. Pharmacy team members do not always discuss incidents from other areas of the company. This means they are missing opportunities to learn and reduce the risk of similar incidents.

Inspector's evidence

Staff numbers in the pharmacy are: one full time pharmacist, one full-time pharmacy technician, who is the manager, one full-time trainee dispenser' one part-time dispenser, Monday, Tuesday, Wednesday 9am to 4.30pm and one part-time delivery driver. Staff members were observed to manage the workload. Staffing levels had been reviewed recently as the pharmacist was leaving at the end of the current week and the pharmacy technician was leaving in two weeks. A pharmacist already working for Well was due to start soon, and a new manager who would be a trainee dispenser had been appointed. The part-time dispenser had planned annual leave for two weeks at the same time as the pharmacy technician was leaving. The pharmacy had contacted the area manager to try and arrange cover, and so far one week was covered.

Although the pharmacy was replacing all the hours that were being lost, pharmacy experience and expertise was being lost. The pharmacy provided protected learning time at the start of week for the trainee dispenser to undertake her accredited training. Monthly e-expert modules were completed as soon as possible after receipt. These were accessed electronically by password. This meant that each member of staff had a record of training undertaken and SOPs read, and any tailored training was available there. The trainee dispenser described using the local minor ailments formulary, NHS Education for Scotland (NES) 'Common Clinical Conditions', and the book, 'Counter Excellence Plus' to help make decisions when providing advice and medicines to people over-the-counter, including the minor ailments service. She described how she shared her learning with her colleagues on the job. An example was described of a staff member using the British National Formulary (BNF) to determine the correct dose for an ambiguously prescribed medicine. This ensured the person received the correct therapeutic dose. A Staff member discussed this fully with the patient to ensure it was correct and that the patient understood how to use it. Staff development meetings were not held. The pharmacy technician described a tool that was available for performance development, but it had not been used yet.

The various individuals were observed going about their tasks in a systematic and professional manner. Team members asked appropriate questions when providing over-the-counter medicines. They were observed to provide effective advice and counselling. Team members described sharing incidents and having open conversations. They were open about a recent dispensing error when describing it to the inspector. They understood the importance of reporting mistakes. And they were comfortable owning up to mistakes. The pharmacy team did not discuss routine communication and incidents for sharing that were received from head office e.g. 'Share and Learn' documents. These were observed to be filed and the one from two months previously was seen. In it the pharmacy was advised to introduce

strategies to avoid incidents happening in this pharmacy. Some of these had not been implemented e.g. a dispensing error involving similar items – this pharmacy only stocked one of these items, but the recommended sticker had not been placed in front of it. Another example recommended placing a sticker in front of Daktarin oral gel, reminding team members that it should not be used with warfarin. The team had not implemented this. Pharmacy team members were not all aware that these documents were on the intranet.

There was a whistle blowing policy that all were aware of, and team members knew how to raise concerns. An incident was described where a concern had been raised with the area manager and resolved. There was frequent on the job discussion and an open environment where team members described talking about anything. They knew how to contact the superintendent pharmacist and the local NHS controlled drug accountable officer.

Targets were set for various parameters. These did not have a negative effect on patients. The chronic medication service was promoted to people who team members believed would benefit from it.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is safe and clean, and suitable for its services. The pharmacy team members use a private room for some conversations with people. People cannot overhear private conversations. They also use a discreet area for some conversations and supervised consumption of medicines. The pharmacy protects people's information. The pharmacy is secure when closed.

Inspector's evidence

These were average sized premises including an adequately sized dispensary. There was a rear area that was used for the management and storage of multi-compartmental compliance packs. Pharmacy team members could prepare these in this area with minimum distraction. The pharmacy had replaced the flooring, some fittings and toilet over recent months which had improved hygiene. 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 clean, hygienic and well maintained.

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 clean and tidy, and the door closed providing privacy. The door was kept locked to prevent unauthorised access. There was 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 that they can all use its services. The pharmacy team provides safe services. Team members give people information to help them use their medicines. They provide extra written information to people with some medicines.

The pharmacy gets medicines from reliable sources and stores them properly.

Inspector's evidence

There was good physical access by means of a flat entrance and team members gave people assistance with the door which was visible from the medicines counter. Services provided were displayed. The pharmacist spoke a few European languages and had a basic understanding of others. She explained that she had sometimes used Spanish to communicate with people in the pharmacy. A hearing loop in working order was available. Large print labels could be provided to people with impaired vision. Leaflets on a range of topics were available.

All staff members wore badges showing their name and role. Dispensing work flow was observed to be logical and smooth with baskets used to segregate patients' medicines and prescriptions. 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, and the pharmacy team used a documented owings system.

There was a delivery service and signatures were obtained on receipt. The pharmacy team members did not know how items requiring cold storage were stored in transit. Multi-compartmental compliance packs were managed on a four-weekly cycle with four assembled at a time. Team members carried out this task in a separate area where there was little distraction. There were assembled, checked and stored in this area. The dispenser or pharmacy technician ordered replacement prescriptions when the third supply was made. The pharmacy technician checked prescriptions for accuracy and completeness when they were received. A part-time dispenser was trained and competent to deputise. Packs were assembled the week before the first one was required. Changes were noted, often on a 'Post-it'. When a staff member had made the change the backing sheet and templates were changed, sometimes using correction fluid. Team members did not keep a running chronological list of changes for all patients. Team members explained that they were not following the SOP exactly. They had agreed with the area manager to continue in the manner they were as there was about to be staff change. They felt that making changes at this time would increase more risk. At the time of inspection, the team were trying to work two weeks ahead with these packs due to forthcoming staff changes. Patient information leaflets (PILs) were supplied with the first pack of each prescription. Tablet descriptions were on backing sheets. The team members attached backing sheets with two staples, so they could become detached. They put names and dates of supply on spines to facilitate safe supplies.

Methadone instalments were poured by a dispenser using a MethaMeasure pump device, and checked by a pharmacist, then supervised or supplied by any team member. The pharmacist usually supervised consumption. This took place at a hatch toward the rear of the premises in a discreet area close to the consultation room. When prescriptions were received, data was input by any staff member as all were trained and competent to do this. There were a variety of other medicines supplied by instalment. These were dispensed in their entirety and individually bagged with date of supply. They were stored

on designated shelves in named baskets.

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 pharmacist described a person who had an unusual blood result. She believed it could be due to poor compliance. She suggested to the GP that the person might benefit from multi-compartmental compliance packs, so this was put in place. The valproate pregnancy prevention programme was in place. The pharmacist had undertaken a search of patient records to identify any relevant people and there were none. She described how she would address and advise patients if required. 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. Team members typed this information on to labels which were attached to relevant dispensed medicines.

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 was one person receiving medicines on a chronic medication service (CMS) serial prescription. The pharmacy was registering very few people for the service now as they believed that all eligible people were probably registered. They had identified very few pharmaceutical care issues. Occasionally the pharmacist discussed how to manage missed doses with people.

The pharmacist usually delivered the minor ailments service (eMAS). She could hear requests from the dispensing/checking bench which was immediately behind the medicines counter. The pharmacist also undertook all smoking cessation consultations. There were currently two people accessing the service, one was taking Champix, and the other on nicotine replacement therapy. Consultations were undertaken in the consultation room and the pharmacist discussed with people which product they would like. During the inspection a new person presented to access service, but when the pharmacist discussed it with her, it was decided she was not yet ready to start the program.

Invoices were observed from licensed suppliers such as Bestway and Alliance.

The pharmacy did not comply with the requirements of the Falsified Medicines Directive (FMD). All team members had read information including a SOP on the process. A new computer system was being installed in five months. The FMD process was expected to be implemented then. (The requirements had been in place for three months at the time of inspection.)

Records of date checking and stock rotation were observed, and items inspected were found to be 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 two CD cabinets. Dispensed items and obsolete items were segregated. 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 in the company 'Super' folder. 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. The pharmacy replaces equipment that no longer works.

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.

The pharmacy had recently replaced the CCTV system when it stopped working. The new system provided a much clearer picture.

The pharmacy kept a carbon monoxide monitor in the consultation room where it was used with people accessing the smoking cessation service. The local health board maintained this.

Crown stamped measures were kept by the sink in the dispensary, and separate marked ones were used for methadone. There was a MethaMeasure pump available for methadone use and this was cleaned, and test volumes poured each day. Clean tablet and capsule counters were also kept in the dispensary. 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 inaccessible to the public. 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.	