General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Leven Pharmacy, 12-14 Commercial Road, LEVEN, Fife, KY8 4LD

Pharmacy reference: 1042115

Type of pharmacy: Community

Date of inspection: 11/04/2019

Pharmacy context

This is a community pharmacy set in a row of shops in a town. The area is growing due to new homes being built on the outskirts. A mixture of people uses the pharmacy, particularly older people. But there are increasing numbers of young families moving into the area. The pharmacy dispenses NHS prescriptions and sells a range of over-the-counter medicines. It also supplies medicines in multi-compartment medicine devices. Other services that the pharmacy offers include the chronic medication service (CMS), minor ailments service (eMAS), and blood pressure measurement.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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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

Pharmacy team members follow processes for all services to ensure that they are safe. The pharmacy is looking at all processes and making some changes to make them safer. Pharmacy team members record mistakes to learn from them. They review these and make changes to avoid the same mistake happening again. The pharmacy keeps all 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/tasks. They had been read and signed by relevant staff members. They were reviewed every two years and were signed off by the pharmacy superintendent. Staff roles and responsibilities were recorded on individual SOPs. Additionally, there was a folder containing other information and details of some other processes. This included National Pharmaceutical Association (NPA) patient safety updates, error analysis, near miss analysis, pharmacy audits, staffing, workload and distribution, time taken for various processes, labelling different prescription types e.g. undertaking labour-intensive labelling at times when there were more team members working, confidentiality, working within competence, duty of candour, local NHS services, requirements of the Falsified Medicines Directive (FMD), and general data protection regulations (GDPR).

The pharmacist undertook frequent audits of all aspects of the pharmacy, particularly timing different activities to ensure that adequate time was allocated, and enough team members were available.

The pharmacist and team members described dispensing as a high-risk activity and used available data to spread the workload as evenly as possible to minimise risks. Footfall had been measured and displayed graphically, showing a 'double bell' curve distribution. This resulted in bulk dispensing, such as collection service prescriptions, being undertaken at quieter times. A lot of labelling of collection service prescriptions was undertaken before the pharmacy opened. 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.

Near miss logs were kept and error reporting was in place. Most, but probably not all near misses were recorded. These were not frequently reviewed to identify trends or repeat incidents, but annual analysis was undertaken. The pharmacist explained that wrong drug was the main problem with wrong strengths being second. Examples of items that had been separated on shelves to minimise repeat incidents were pravastatin and pantoprazole. There had been an incident involving a multicompartment medicine devices a few months previously. A significant event analysis and review of all aspects of this process had been undertaken with all team members involved. This had resulted in several changes being implemented and all staff briefed on these. One change was that completed devices were now packed into clear bags to enable the label on the pack to be seen at the point of supply. Audits related to these devices were frequently undertaken to ensure they continued to be provided in as safe a manner as possible. Audits were also used to ensure that this was the best way for people to receive their medicines.

A recent audit had been undertaken to consider if more bulk working could be done to free up pharmacist time to pursue more clinical activities.

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

There was a complaints procedure in place and surveys were undertaken periodically. A recent survey with an emphasis on waiting time for dispensed medicines had been done. There had been good uptake with almost 40 responses. There were no negative comments. This demonstrated that people were content with the waiting times. This was important to the pharmacist as there was another pharmacy closer to the GP practice.
Indemnity insurance certificate was in place, expiring March 2020.

The following records were maintained in compliance with relevant legislation: responsible pharmacist notice displayed; responsible , pharmacist log; private prescription records.including records of emergency supplies and veterinary prescriptions; unlicensed specials records; controlled drugs registers, with running balances maintained and regularly audited; records of patient returned controlled drugs. ThePMR was backed up and alterations to records were attributable, by pharmacists' initials on paper records, and password required for an electronic controlled drug register.

Staff members were aware of the need for confidentiality and had signed a clause within their contracts of employment. No person identifiable information was visible to the public. Confidential waste was segregated for secure destruction.

There was awareness of safeguarding, and NPA guidance was displayed in the dispensary wall.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough qualified and experienced staff to safely provide services. The pharmacy compares staff numbers and qualifications to how busy the pharmacy is. The pharmacy makes changes. This ensures skilled and qualified staff provide pharmacy services. The pharmacy provides time for team members on training courses to complete these. Team members can share information and know how to raise concerns if they have any. They are able and encouraged to make suggestions to improve services. The pharmacy team members discuss incidents. They learn from them to avoid the same thing happening again.

Inspector's evidence

Staff numbers present at time of inspection: two pharmacists, the superintendent pharmacist three and a half days per week, and a regular locum pharmacist two days per week; three full-time dispensers; two part-time dispensers (each 22.5 hours and one was a trainee); one full-time medicines counter assistant; one part-time delivery driver. Certificates of qualification were displayed.

Staff members were observed to manage the workload. Staffing levels were regularly reviewed. Following recent changes with resignation, absence and maternity leave, there had been recruitment. Rotas were used to manage staff levels depending on workload. The trainee dispenser was given time at work to undertake her course. She was also well supported by colleagues and supervised by the pharmacist – this was observed. She asked lots of questions and there was ongoing coaching on-the-job.

No regular structured training or development but relevant information was read and shared when it was received into the pharmacy. Examples were Medicines and Healthcare Regulatory Authority (MHRA) drug alerts and recalls. Regular medicines counter training modules were received, and the medicines counter assistant read these. The various individuals were observed going about their tasks in a systematic and professional manner.

Team members present during the inspection described an open working environment where they could share information and feel comfortable owning up to mistakes. A recent dispensing error been discussed amongst all team members with areas for learning identified.

Members described feeling able to share information or raise concerns amongst themselves, with the locum pharmacist and superintendent pharmacist. No examples of concern were described but appropriate responses were given to scenarios posed. Team members knew that any controlled drug (CD) incidents or concerns must be reported to the NHS CD accountable officer. Periodic meetings were held with all team members if there were topics to be discussed.

The pharmacist welcomed feedback from all team members and had sent a letter to all describing an audit to be undertaken and asking for suggestions. He had asked his regular locum pharmacist for opinion before finalising the audit. A team member had suggested listing items ordered for prescriptions, so that these could be taken straight from the order as it arrived rather than putting them to shelf first. This was being considered. The medicines counter assistant described being given a degree of autonomy to run the retail area. She had suggested trying a feature area at the front of the

premises which had been agreed, and she was currently using this to promote suntan merchandise.

Targets were not set.

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. The pharmacy is secure when closed.

Inspector's evidence

These are small premises that made use of two separate small dispensing areas to separate different dispensing activities. 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 premises were observed to be clean, hygienic and well maintained.
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.
The pharmacy was alarmed, had CCTV, and had panic alarms. Shutters protected the front door and windows when the pharmacy was closed. The back door was locked, bolted and alarmed.
Temperature and lighting were comfortable.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy has measures in place to ensure its services are accessible to all people. The pharmacy team provides safe services. Team members give people information to help them use their 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 assistance given as required. Services provided were displayed.
Large print labels provided for people with impaired vision, and helping dogs were welcome in the pharmacy. Signposting to other services was described e.g. needle exchange. Leaflets on a range of topics were available. All staff members wore badges showing their name and role.

Dispensing was recognised as a high-risk activity, and the main activity delivered in the pharmacy. As noted above the pharmacist had done a lot of work auditing workflow and time taken for different activities to streamline and improve the efficiency of dispensing. Workflow round the dispensary had been designed to be smooth and as efficient as possible. Designated areas were used for different activities, baskets were used to separate each patient's medicines and prescriptions, labels were used to highlight high-risk items and those requiring special storage, and pharmacist information forms were used to share information with pharmacist.

The pharmacist and dispenser started work before the pharmacy opened, to label prescriptions without distraction. Where possible the pharmacist labelled, enabling a clinical check to be undertaken at that stage. 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 and signatures were obtained on receipt. This was well managed, using additional bag labels on the delivery sheet.

Multicompartment medicine devices were managed on a four-weekly cycle with four assembled at a time. Each dispenser had their own cohort of devices, which provided some continuity for communication with prescribers or patients was required. This also ensured that all team members were equally skilled at this task which provided safe and effective cover during absence. It also ensured that staff members undertook a variety of tasks which avoided boredom or complacency. Patient information leaflets (PILs) were supplied with the first device of each prescription. Basic tablet descriptions were included. There was a robust process followed for the management of the devices, with checks at various points. Medication was checked by a pharmacist before and after it was placed into the devices, and checks were made between prescriptions and backing sheets. Dispensers sealed devices with few tablets but those with many tablets were left open for the pharmacist to seal after checking.

At the time of inspection, care homes' medicines were supplied in multicompartment medicine devices, but, in line with Care Inspectorate guidance, these were moving to original packs over the following

months. This would reduce workload as managing these devices was time-consuming. Typically, devices for people in residential care contained less medicines than people in their own homes.

Methadone instalments were poured by a dispenser and checked by a pharmacist using a hand pump when people presented at the pharmacy. When prescriptions were received, the data was entered onto the instalment software on the computer by a dispenser and checked by a pharmacist. There was a hatch to the dispensary which was used for supervision. People rang a bell and were asked for their name before the instalment was poured. It was then doublechecked, and the person was asked for their address and date of birth.

There were a variety of other medicines supplied by instalment. These were assembled a few days or a week at a time, placed into labelled bags and sealed. They were stored in baskets until supply. Each day that day's instalments were moved to the front of the dispensary.

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. There was knowledge and awareness of the valproate pregnancy prevention program, but there were currently no relevant patients on this medication.

Medicines were supplied to GP practices on stock orders forms. These were not all particularly local to the pharmacy. The pharmacy did not have a wholesale dealer's license.

NHS services followed the service specifications and patient group directions (PGDs) were in place for unscheduled care, pharmacy first, smoking cessation, emergency hormonal contraception, and chloramphenicol ophthalmic products. These were current, and the pharmacists had been trained and signed them.

There were around 240 patients receiving medicines on chronic medication service (CMS) prescriptions. These were dispensed when people came to the pharmacy. Previously, these had been dispensed in advanced, but there were many examples of people not collecting them. Attempts had been made to synchronise medicines but that was challenging as people did not always want all their items.

Registration was ongoing. The pharmacist had discussed this service with the practice manager when the local GP practice had relocated. Few pharmaceutical care issues were identified, as most people were found to be knowledgeable about their medicines and conditions. Staff members were empowered to deliver the minor ailments service (eMAS) within their competence. Many requests were referred to the pharmacist. Paediatric paracetamol doses were on the dispensary wall as an aide memoir. All smoking cessation consultations were delivered by a pharmacist.

Invoices were observed from licensed suppliers such as AAH and Alliance. The pharmacy was not yet compliant with the requirements of the Falsified Medicines Directive (FMD). The superintendent pharmacist explained that he had undertaken the required paperwork and registered, but not yet got the equipment. 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/in drawers. Items requiring cold storage were stored in three fridges with minimum and maximum temperatures monitored and action taken if there was any deviation from accepted limits. The fridge had been replaced the previous year and all stock destroyed when the temperature had gone out of range over a prolonged period.

Controlled drugs (CDs) were stored in five CD cabinets. The pharmacy always kept a stipulated amount of regularly used medication to minimise the chance of running out during any shortage or disruption to

supply. The keys were kept on the pharmacist during the day and in a key safe at night. 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 IT access allowing online resources to be used.

Equipment required to deliver pharmacy services was kept in the consultation room where it was used with patients accessing these services. This included a carbon monoxide monitor maintained by the health board, and a blood pressure meter which was replaced as per the manufacturer's guidance.

Crown stamped measures were kept by the sink in the dispensary, and separate marked ones were used for methadone. There was a pump available for methadone use and this was cleaned, and test volumes poured daily, and it was calibrated annually. Clean tablet and capsule counters were also kept in the dispensary, and separate marked ones were used for cytotoxic tablets.

Paper records were stored in the consultation room is locked, and in the dispensary, inaccessible to people. 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.