General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Lynton Chemist, 17-18 Lee Road, LYNTON, Devon, EX35 6BP

**Pharmacy reference:** 1030778

**Type of pharmacy:** Community

**Date of inspection:** 01/10/2019

## Pharmacy context

The pharmacy is located on the high street of the village of Lynton in North Devon. It dispenses NHS and private prescriptions. It dispenses medicines into multi-compartment compliance aids for people living both in their own homes and in one small care home. The pharmacy offers advice on the management of minor illnesses and long-term conditions. It provides additional services including Medicines Use Reviews (MURs), the NHS New Medicines Service (NMS) and flu vaccinations.

## 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 have written procedures for all the work it does. This means that the team members may not know the safest and most effective way to work. Team members do not record their errors and consider why they have happened. So they may miss opportunities to learn from them and improve. |
| | | 1.2 | Standard not met | The pharmacy does not review the safety of its services. This may mean that they lose the opportunity to identify themes, learn from errors and stop similar errors from happening again. |
| | | 1.4 | Standard not met | The pharmacy does not always respond to feedback it receives and make the changes needed to improve. |
| **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 not all met | 4.2 | Standard not met | The pharmacy does not always follow its written procedures when supplying medicines. And this could lead to medicines being supplied incorrectly or not as required by law. People do not always receive additional advice or checks when they receive high-risk medicines. |
| | | 4.4 | Standard not met | The pharmacy does not have a robust process for receiving recalls and drug alerts. |
| **5. Equipment and facilities** | Standards met | N/A | N/A | N/A |

## Principle 1 - Governance **Standards not all met**

### Summary findings

The pharmacy does not adequately identify and manage its risks. Team members do not record their errors and review them. This may mean that they lose the opportunity to learn from them and stop similar errors from happening again. The pharmacy has written procedures for most of the work it does. But the steps needed for some important tasks are not documented. This means that the team members may not know the safest and most effective way to work. The pharmacy does not always respond to feedback it receives and make the changes needed. The pharmacy mostly keeps up-to-date records as required by the law. But it omits some details which may make it difficult to show exactly what has happened. The pharmacy keeps people's private information safe, but it does not explain how it will be used. Pharmacy team members know how to protect the safety of vulnerable people. The pharmacy has insurance in place so people are protected if things go wrong.

### Inspector's evidence

The pharmacy did not have adequate processes in place to identify and manage its risks. The responsible pharmacist (RP) and the team did not record near miss errors, despite a log being available. The most recent entries had been made in March 2019, and prior to that date, no errors had been recorded since 2018. After initially saying that the pharmacy team made no errors, the RP said that when he did find an error he gave it back to the dispenser to be rectified. No written patient safety reviews had been completed. Dispensing incidents were reported by the superintendent pharmacist (SI), who was also the owner, when she was made aware of them. But one of the two recent dispensing incidents, which had prompted the inspection, had not been reported to the National Reporting and Learning System (NRLS). The RP was unaware of the NRLS and the need to report incidents. There was no evidence that actions were put in place to prevent a reoccurrence of errors. For example, stock of a drug recently subject to a dispensing incident had not been highlighted or moved. Look-alike, sound-alike drugs were not highlighted or segregated in any way.

The pharmacy had standard operating procedures (SOPs) for most of the activities it carried out. But the SOP for operating in the absence of the RP was missing. There was a cover sheet and a sheet signed by the SI, but no SOP present. There was also no SOP to cover the supply of medicines to care homes. The RP said that he had read all of the SOPs but his signature was not present on any of them. The dispenser, who had started working at the pharmacy three weeks before the inspection had also not signed to say that she had read all of the relevant SOPs.

The pharmacy team were unclear if they collected feedback through a yearly community pharmacy patient questionnaire (CPPQ) survey. All team members present had worked in the pharmacy for less than four months. The pharmacy page on NHS.uk displayed no CPPQ survey results. The pharmacy did receive verbal feedback from the people who used it. A complaints procedure was displayed. There had been several complaints in recent months about the service provided, including from the local GP practice. Complaints were passed to the owner who usually responded directly. An official concern had been raised which had prompted the inspection. The person raising the concern did not feel that her concerns had been listened to and appropriate changes made.

Public liability and professional indemnity insurance were provided by the NPA, with an expiry date of 30 April 2020.

Records of the RP were held on the PMR system but were incomplete. There were no instances over the previous month where the RP had signed out at the end of the shift. The incorrect RP sign was displayed at the start of the inspection. Records of private prescriptions were held in a bound book and were in order. No records of emergency supplies were seen, although the SI later confirmed that these were also recorded in the private prescription book. No records of unlicensed specials records were seen. The SI later provided assurances that these were stored in a locked cabinet. Controlled drug (CD) registers were generally completed appropriately, but there were some instances of headers not being completed. The address of the supplier was not always completed in entries of receipt of CDs. Balance checks were completed sporadically. The register for morphine sulphate injection 10mg/ml appeared to show that 3 ampoules had been supplied to a person on 3 June 2019, then returned intact on 17 June 2019. These had then been returned to stock. The RP thought that they may have been left in a 'just in case' box on the dispensing bench for the 12 days. But he could not explain why an entry had been made to show that they had been given to the person if that was the case.

No information governance policy or SOP was seen. The dispenser had received training on IG and general data protection regulations in a different place of work. There was no privacy policy or fair data use statement displayed to inform people how their data would be processed and used. But patient data and confidential waste was dealt with in a secure manner to protect privacy and no confidential information was visible from customer areas. Smart cards were used appropriately.

All staff were trained to an appropriate level on safeguarding. The RP had completed the Centre for Postgraduate Pharmacy Education (CPPE) level 2 safeguarding training. A safeguarding policy was in place and signed by staff and local contacts could be accessed online. Staff were aware of signs of concerns requiring escalation.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

The pharmacy has enough staff to manage its workload. Team members receive training for their roles. They keep their skills and knowledge up to date and are supported in their development. Team members suggest and make changes to improve their services. They communicate well with each other.

### Inspector's evidence

Staffing was adequate on the day of the inspection and consisted of the RP, who was a regular locum, an NVQ2 level dispenser and a trainee medicines counter assistant (MCA). The team felt they could usually comfortably manage the workload with no undue stress and pressure. Pharmacy team members had clearly defined roles and accountabilities and tasks were allocated to individuals daily. They worked regular days and hours. Absences were usually covered rearranging shifts, or by part-time staff increasing their hours.

The MCA was completing an accredited training course. She usually had time to complete her learning in work time and was supported by the SI when she was in the pharmacy. Team members were seen to provide appropriate advice when selling medicines over the counter. They referred to the RP for additional information as needed.

The staff felt able to raise concerns and give feedback to the owner, but they did not always feel that their ideas were listened to. Team members were aware of the escalation process for concerns and a whistleblowing policy was in place. The RP said that no targets were set. The RP was able to use his professional judgement to make decisions and described that all services undertaken were clinically appropriate.

## Principle 3 - Premises ✔ Standards met

### Summary findings

The pharmacy provides a safe, secure and professional environment for people to receive healthcare. The pharmacy has a soundproofed room where people can have private conversations with members of the pharmacy team. The pharmacy is adequately secured to prevent unauthorised access.

### Inspector's evidence

The pharmacy was located on the main street of the village of Lynton in North Devon. A spacious retail area led to the healthcare counter. A small waiting area was available which had two chairs. Additional chairs could be sourced from the consultation room if needed. The dispensary was galley style and was to the left of the retail area. It was appropriately screened to allow the preparation of prescriptions in private.

A consultation room was available. It was accessed by walking next to the area where prescriptions awaiting collection were stored. There was potential that prescriptions could be seen by people walking into the consultation room. But to mitigate this risk, the pharmacy team took care to store prescriptions facing the wall, making the details harder to view. There was a small stock room containing a kitchen area leading from behind the healthcare counter. The basement was accessed by a narrow flight of stairs and housed the lavatory and storage space. The non-public areas of the pharmacy smelt musty and damp.

The dispensary shelves were generally well-organised. Stock was stored alphabetically, although there were multiple baskets under a bench of split packs waiting to be put away. The pharmacy was cleaned by the pharmacy team. It was clean and well-presented on the day of the inspection. The lighting and temperature were appropriate for the storage and preparation of medicines.

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

### Summary findings

The pharmacy does not always follow its written procedures when supplying medicines. And this could lead to medicines being supplied incorrectly or not as required by law. People do not always receive additional advice or checks when they receive high-risk medicines. The pharmacy obtains its medicines from reputable suppliers and stores them securely. But they do not regularly check that they are still suitable for supply. The pharmacy does not have a robust process for receiving recalls and drug alerts. This means that there is a risk that people may receive date-expired or recalled medicines. The pharmacy is accessible and advertises its services appropriately. The pharmacy accepts unwanted medicines and disposes of them appropriately.

### Inspector's evidence

The pharmacy was wheelchair accessible, as was the consultation room. Services provided by the pharmacy were advertised on the wall of the pharmacy. The pharmacy made adjustments for those with disabilities including printing large print labels. Team members would communicate with people who were hard of hearing using pen and paper if needed. The dispenser explained that if a person requested a service not available at the pharmacy, she would refer them to the closest pharmacy. Due to the rural location of the pharmacy, the nearest alternative pharmacy was approximately 30 minutes away. The dispenser said that she would therefore phone ahead to ensure it could be provided there.

Baskets were used to store prescriptions and dispensed medicines to prevent transfer between patients as well as organise the workload. There were designated areas to dispense walk-in prescriptions and owings. The checking bench was cluttered and the RP emptied the contents of baskets on to it to check. The RP said that he sometimes performed a self-check, without taking a mental break between the dispensing and checking process. This had resulted in some near misses which were picked up by the dispenser when bagging items. The labels of dispensed items were initialled when dispensed and checked. The pharmacy supplied multiple packs of the same medicines taped together with a single label applied. For instance, 84 amlodipine 5mg tablets was dispensed as three boxes of 28 taped together, with a label for 84 attached. The SI said on the telephone after the inspection that this was historical practice from the previous owner and committed to ensure all boxes were individually labelled in future. It had been set as the default on the PMR system that no bag labels were printed. Therefore, completed bags were stored simply with the prescription attached, increasing the risk of handout errors. A number of prescriptions were dispensed using the repeat dispensing (RD) system. One RD prescription was dated 10 September 2018 and had been dispensed on 30 September 2019, making it passed the 12-month expiry and out of date. In order to improve the effectiveness of the RD system, the dispenser had started using Google calendar to record when people's next batch was due. She then downloaded the prescriptions three days in advance to ensure they were prepared in time for people to collect.

The RP said that he checked the INR for people receiving warfarin. He did not make records of these checks and did not know how to use the notes function on the PMR. He made no additional checks when dispensing other high-risk medicines, such as methotrexate or lithium. He was unaware of the PREVENT valproate pregnancy prevention programme (PPP). He was not clear on his responsibility to ensure woman who were taking valproate and were at risk of pregnancy were using an appropriate form of contraception. A PMR search identified at least one woman who fell within the age range of the

PPP. There were no notes on her PMR to show that a pharmacist had discussed the need for contraception with her.

The process for the dispensing of multi-compartment compliance aids provided for approximately twenty people in the community and the residents of one small care home was acceptable. Each pack had an identifier on the front, and dispensed and checked signatures were available, along with a description of tablets. Patient information leaflets were supplied at each dispensing, or with the first pack of four in the case of weekly supply. When required medicines were dispensed in boxes and the dispenser was aware of what could and could not be placed in trays. A record of any changes made was kept on the patient information sheet, which was available for the pharmacist during the checking process.

Stock was obtained from reputable sources including Alliance, and AAH. Specials were obtained from both IPS Specials. The pharmacy had the hardware and software to be compliant with the Falsified Medicines Directive (FMD) and were registered with V-Care systems but were not currently scanning compliant packs. The SOPs had not yet been amended to reflect the change in process that scanning products would bring. The dispensary shelves were generally tidy and organised. The stock was arranged broadly alphabetically. But there were multiple baskets of stock under the dispensing bench which needed to be put away, including some short-dated stock. The dispenser had started the date checking process earlier that week. She was unclear when stock had last been checked as there was no matrix or record kept. Several items of date-expired stock were found including Pramipexole 0.18mg tablets expiring June 2019 and Cholestagel tablets expiring May 2019. Short dated items were not routinely highlighted, for example a pack of Indoramin tablets expiring October 2019. A bottle of paracetamol tablets was found on the shelf not bearing a batch number or expiry date.

The pharmacy did not have a robust process in place to ensure that drug alerts and recalls were received. They did not have access to the pharmacy's email account. The RP was not aware of a recent recall of bisacodyl suppositories or aripiprazole oral solution. But no affected stock was found on the shelves.

CDs were stored in accordance with legal requirements. Denaturing kits were available for safe destruction of CDs. Patient returned CDs were recorded in a register and destroyed with a witness with two signatures were recorded. The fridge in the dispensary was clean, tidy and well organised. Records of temperatures were maintained. The maximum and minimum temperatures were within the required range of two to eight degrees Celsius. Staff were aware of the steps taken if the fridge temperature was found to be out of range, which was to monitor every 30 minutes until back in range.

Patient returned medication was dealt with appropriately, and a hazardous waste bin was in use. Patient details were removed from returned medicines to protect people's confidentiality. The pharmacy could arrange for additional collections of pharmaceutical waste as needed.

## Principle 5 - Equipment and facilities ✔ Standards met

### Summary findings

The pharmacy uses appropriate equipment and facilities to provide its services. It keeps these clean and tidy. Computers are used in a way that protects people's private information.

### Inspector's evidence

Validated crown-stamped measures were available for liquids. A range of clean tablet and capsule counters were present, with a separate triangle clearly marked for cytotoxics. Reference sources were available and the pharmacy had online access to materials for the most up to date information. The dispensary sink was clean and in good working order. All equipment including the dispensary fridge was in good working order and PAT test stickers were visible and were in date.
Dispensed prescriptions were stored alphabetically in the dispensary, mostly out of sight of customers. As described in principle three, there was a possibility that prescriptions may be seen by people walking into the consultation room. The dispenser and the MCA were hoping to change the storage arrangements to a retrieval system to better utilise the space and improve confidentiality. Computers were positioned so that no information could be seen by customers, and phone calls were taken away from public areas.

## 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. |