General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Liverpool Road Pharmacy, 79 Liverpool Road, ST. HELENS, Merseyside, WA10 1PQ

Pharmacy reference: 1034714

Type of pharmacy: Community

Date of inspection: 13/12/2022

Pharmacy context

This pharmacy is situated close to the town centre next door to a GP's surgery. In addition to dispensing medicines the pharmacy provides flu vaccinations. And it supplies people with medicines in multi-compartment compliance packs to help them manage their medicines. The pharmacy also supplies medicines against private prescriptions issued by a private online prescribing service. This was a targeted inspection in relation to the pharmacy's association with the online prescribing service, so some pharmacy services and some standards were not covered.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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 is not identifying and managing the risks relating to the online prescribing service. It does not have effective controls in place to make sure the medicines it supplies are appropriate and being used safely
		1.2	Standard not met	The safety and quality of the associated, private, prescribing service is not regularly reviewed and monitored. The pharmacy has not completed any audits to provide assurances that the service is safe.
		1.8	Standard not met	The pharmacy is failing to safeguard vulnerable people because it does not have sufficient safeguards in place to prevent inappropriate supplies of medicines that are liable to abuse and misuse.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website and the website of its associated prescribing service contains inaccurate information. The website of the associated prescribing service also allows people to select a prescription-only medicine (POM) before starting a consultation, which is inappropriate.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy is not able to provide assurance that the online prescribing service it works with is operating safely and responsibly. The pharmacy cannot demonstrate that the medicines it supplies are always appropriate and safe for people.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy works with a private, online prescribing service which is not registered with a UK regulator. But it does not identify or manage the risks associated with the service. It does not have effective checks or controls in place to make sure the medicines it supplies are appropriate and being used safely. And it does not effectively safeguard vulnerable people. So there is a significant risk that the medicines it supplies could be misused and cause harm to people.

Inspector's evidence

The pharmacy dispensed prescriptions for a private online prescribing service. The responsible pharmacist (RP) knew that the prescribers for this service were doctors who were registered with the GMC, but the service was not registered with the CQC. There was no documented service agreement between the pharmacy and the prescribing service provider to define the relationship and terms between them. The pharmacy had started dispensing medicines for the prescribing service since September 2022. There was no evidence of any risk assessments being completed before the service was introduced.

The prescribing service had its own website, which people used to request medicines and access the service. The website allowed people to select a medicine before starting a consultation. People using the website could select from a range of medicines for various conditions then had to open an account before completing an online questionnaire to obtain a prescription. Medicines listed on the website included some that are liable to misuse and abuse.

The pharmacy had a range of standard operating procedures (SOPs) to underpin its services. Team members had read and signed SOPs relevant to their roles. However, there were no specific SOPs to support the provision of services in association with the prescribing service. The pharmacy had not completed any risk assessments to identify, manage or mitigate the risks associated with this service. Nor had any audits been completed to verify the safety and quality of the service being provided. This meant that there was no effective oversight analysis of the prescribing habits, or analysis of the risks associated with the medicines being supplied.

The pharmacy received prescriptions from the prescribing service by email. The RP was not able to confirm whether the prescriptions met the requirements for an advanced electronic signature. The pharmacy also had access to the online questionnaires that patients had completed. The pharmacy dispensed the prescriptions and then sent the medicines by courier directly to the patients. The pharmacy team did not have any other contact with the patients. The responsible pharmacist (RP) explained that if she had any concerns about the prescriptions being issued she could raise them with the prescribing service. For example, the pharmacy had briefly suspended the service when the RP had been concerned about the quantity of zopiclone being ordered, someone ordering modafinil from two different addresses, and the time period between orders in some cases. The pharmacy had then resumed the service when the prescribing service reduced the number of zopiclone tablets to seven per prescription and explained the two different addresses were because of temporary student accommodation. A prescription for Diazepam was present that had not yet been dispensed, and the RP explained this was because she was not satisfied that it was appropriate. There were no records or notes available to show justification for prescribing or why prescriptions had been issued without

contacting the person's regular GP. Analysis of the prescription data (following the inspection) identified several examples of different accounts with the same addresses, which medicines had been supplied to within a short period of time. And there was no policy for a minimum interval between repeat supplies.

The correct RP notice was displayed. The pharmacy had current professional indemnity insurance. A representative from the company's head office confirmed that the indemnity insurers had been notified about the dispensing of medicines for the prescribing service. The pharmacy had a complaints procedure but reported that no complaints had been received about dispensing for the prescribing service.

Records of private prescriptions dispensed and RP records were generally well maintained. But the prescriber details were incorrect on some of the private prescription records seen.

Pharmacists had completed level two safeguarding training and other team members had completed the level one training. This was updated each year with head office notifying team members of the training they were supposed to complete. The company also had a safeguarding policy which team members had read and signed. Local safeguarding contacts were available. However, the pharmacy supplied medicines nationwide for the prescribing service . The RP said she would contact the superintendent pharmacist or the prescribing service if she had any concerns about vulnerable people. The pharmacy did not have a process in place to address the risk of potential abuse and safeguarding people. The pharmacist explained they would refer to the PMR system to ensure early or frequent requests were declined. But the records showed supplies of high-risk medication to different names at the same address. These supplies had not been recognised by the pharmacy. The pharmacy did not have a process in place to highlight similar addresses being used.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage its workload appropriately.

Inspector's evidence

During the inspection, the pharmacy team consisted of the RP, two trained dispensers, a foundation trainee pharmacist, and a pharmacy student. The team appeared able to comfortably manage the workload.

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

Summary findings

Some information on the pharmacy's website and on the website of the associated prescribing service is out of date and inaccurate. The associated prescribing service's website allows people to select a prescription-only medicine prior to having a consultation, which is inappropriate. The pharmacy's premises are clean, secure and provide an appropriate environment to deliver its services. People can have a conversation with a team member in a private area.

Inspector's evidence

The pharmacy was generally clean and tidy, and there was ample workspace. A sink was available in the dispensary. Cleaning was carried out by the team members. Medicines were arranged on shelves in a tidy and organised manner. The room temperature and lighting were adequate for the provision of healthcare. The premises were kept secure from unauthorised access.

A clean, signposted consultation room was available. The room was suitable for private conversations. The door to the room was slightly ajar when not in use which meant there was a risk of unauthorised access.

The pharmacy had its own online website (https://liverpoolroadpharmacy.co.uk). This website gave clear information about the pharmacy's opening times, how people could complain, the pharmacy's contact details and GPhC registration information. However, the details of the superintendent pharmacist (SI) were incorrect. The website had no direct or indirect reference to the prescribing service and there were no options to purchase any medicines from the website.

The website for the associated prescribing service had inaccurate information which stated it was a registered pharmacy with an address in Bedfordshire. But the address given was not a registered pharmacy. It was unclear as to who issued prescriptions with references made to GPhC registered pharmacist independent prescribers (PIPs) reviewing consultation forms and issuing prescriptions. The website allowed people to choose a medicine prior to starting a consultation.

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

Summary findings

The pharmacy is not able to provide assurance that the online prescribing service it works with is operating safely and responsibly. The pharmacy has supplied significant quantities of medicines which are liable to abuse or misuse, including some medicines for long-term conditions that require ongoing monitoring. But the pharmacy team cannot demonstrate that the prescriptions are always appropriate and safe for people.

Inspector's evidence

The pharmacy received prescriptions from the online prescribing service electronically. This was via a dedicated email account through which the pharmacy was able to communicate with the service. Prescriptions were sent through with a copy of the completed questionnaire and a shipping label. The RP could not confirm whether the systems being used were secure and encrypted. She believed that the prescribing service verified people's ID and said she had been provided with assurance that physical ID was checked, but she did not know how this was done

The workflow with this service involved the RP accessing and printing off the prescription, the associated label for the delivery and dispensing labels for the medicines. When details were added to the electronic patient medication records the team checked to see the interval between supplies. The medicines were then dispensed and accuracy-checked before being packaged for delivery. Medicines were delivered to people in the UK by a tracked courier service. In the time that the pharmacy had provided the service there had only been one failed delivery.

239 prescriptions had been issued by the online service and dispensed by the pharmacy between 27 September 2022 and 12 December 2022. There was only one item prescribed per prescription form. These included:

- 20 prescriptions for Zopiclone 7.5mg tablets.
- 217 prescriptions dispensed for Modafinil. (39 for 100mg and rest 200mg)
- One prescription each for Finasteride and Salbutamol

Modafinil is a stimulant which is licensed only for treatment of narcolepsy. Current guidance is that it should not be used for shift-worker sleep disorder. However, the prescribing service website mentioned its use for shift-work sleep-disturbance and several of the questionnaires seen suggested it was being used for this purpose. Modafinil can cause problems if it is used to treat people with a history of substance misuse or some mental illnesses. It can also cause some heart problems, so people taking it need ongoing monitoring including blood pressure checks and ECGs. When people completed the questionnaires, they had to self-declare that they were suffering from narcolepsy. But there was no evidence of a full medical history being taken and no evidence an ECG having been taken. The RP did not know whether these checks were made by the prescribing service. The questionnaires also asked people to agree to monitor their blood pressure and heart rate but there was no evidence of any checks or follow-up. There are also risks if Modafinil is used during pregnancy and it can reduce the effectiveness of some contraceptives. But the pharmacy was not able to provide assurance that the prescribing service had addressed these risks before issuing the prescriptions.

Zopiclone is used to treat insomnia. It is known to be liable to abuse and misuse. Guidance for prescribing in the elderly states that Zopiclone should be prescribed initially at the lower 3.75mg strength. But there were examples of people aged 70 and 72 years old being given Zopiclone 7.5mg. Some of the earlier prescriptions had been for 28 tablets but the RP had raised concern and the maximum quantity had subsequently been reduced to 7 tables per prescription.

Finasteride is used to treat male pattern hair loss. A detailed history is required to assess the severity and impact of hair loss, and to identify possible risk factors. There is a need to consider alternative diagnosis if there is rapid onset of hair loss, inflammation, scaling or scarring of the scalp, and exposure or change to medication. The person prescribed Finasteride had declared on the questionnaire that their hair loss was in patches, and they had an itchy, sore scalp. They had suffered from sudden, unexpected or complete hair loss. And the hair loss could be explained by medication, dietary matter or illness. The answers would suggest further intervention was required. There was no evidence that this had occurred, and medication was prescribed and dispensed based on these details with no pharmaceutical intervention.

The RP was unaware whether the prescribers ever contacted people as part of the consultation process There was no evidence of the pharmacy counselling people on the use of their medication. The RP explained that the pharmacy had never been contacted by anyone they had supplied medicines to for this service.

People using the service were asked for consent to contact their regular prescribers. But there was no evidence that any had been contacted and for most of the questionnaires seen, consent had not been provided. There were no records or notes to show justification for prescribing or why prescriptions had been issued without consulting the person's regular GP.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

This Principle was not inspected on this occasion.

Inspector's evidence

This Principle was not inspected on this occasion.

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.