General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Littleover Pharmacy, 562 Burton Road, Littleover, DERBY, Derbyshire, DE23 6DF

Pharmacy reference: 1030324

Type of pharmacy: Community

Date of inspection: 02/03/2022

Pharmacy context

This community pharmacy is situated in a row of local shops in the Littleover area of Derby. It dispenses NHS prescriptions and sells a range of over-the-counter medicines. And it works with a private online prescribing service. This inspection was in response to information received by the GPhC about the pharmacy's association with the online prescribing service. And the inspection was targeted at the pharmacy's activities in relation to this service, so other aspects of its services were not inspected and not all principles were assessed. The inspection took place during the COVID-19 pandemic.

Overall inspection outcome

Standards not all met

Required Action: Statutory Enforcement

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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 identify and manage the risks associated with the online prescribing service which it works in partnership with and is operating outside of UK regulatory control. It cannot show that it has adequate systems or risk assessments in relation to the prescribing service to ensure that the supplies of prescription medicines are safe.
		1.2	Standard not met	The pharmacy cannot provide assurance that it effectively monitors and audits the supply of medicines issued by the online prescribing service to prevent misuse, abuse or overuse
		1.3	Standard not met	The pharmacy's responsibilities in relation to the prescribing service are not made clear or documented in the service agreement. It relies heavily on the prescribing service to make sure that the medicines it supplies are clinically appropriate for the people using the service. But the pharmacy cannot provide adequate assurance that the prescribing service's working practices are safe.
		1.6	Standard not met	The pharmacy does not keep private prescription records for the prescribing service or retain the private prescriptions, and there is a risk that the pharmacy may not be able to easily access this information. For example, the prescribing service could refuse to provide them, or it could cease to trade. And the private prescription records provided do not contain all of the details, as required by law.
		1.8	Standard not met	The pharmacy does not have sufficient safeguards in place to make sure that supplies of high-risk medicines are appropriate or that these medicines are not being abused or misused. This means vulnerable people may be using the online prescribing service to obtain medicines which are not clinically appropriate and

Principle	Principle finding	Exception standard reference	Notable practice	Why
				could cause them harm.
2. Staff	Not assessed	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy is partnered with a prescribing service that operates a website that is arranged so that a person can choose a medicine and its quantity before there has been an appropriate consultation with a prescriber. This means people may not always receive the most suitable treatment.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy supplies large quantities of medicines which are liable to abuse or misuse or require ongoing monitoring, without obtaining sufficient information or making enough checks to make sure they are suitable for the person concerned. The pharmacy cannot provide assurance that the online prescribing service proactively shares all relevant information about prescriptions with other health professionals involved in the care of the person.
5. Equipment and facilities	Not assessed	N/A	N/A	N/A

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

Summary findings

The pharmacy does not manage and identify the risks associated with working with an online prescribing service that falls outside of the UK regulatory framework. It has not completed appropriate risk assessments before working with the prescribing service to ensure that its working practices are safe. The pharmacy relies on the prescribing service to make sure that supplies of medicines are clinically appropriate for people using the service, but it cannot provide assurance that adequate safeguards are in place. This means that people may be able to access medicines which may not be suitable and could cause them harm.

Inspector's evidence

The pharmacy was a traditional community pharmacy which held an NHS contract. The pharmacy had been owned by Littleover Healthcare UK Ltd since November 2020. There was one company director who was also the superintendent pharmacist (SI) and a pharmacist independent prescriber. He worked regularly at the pharmacy as a responsible pharmacist. The pharmacy had a dispensary and shop area downstairs which was used to dispense NHS prescriptions, carry out NHS funded services and selling medicines and other products. A second dispensary was located upstairs and was used for dispensing prescriptions for the online prescribing service that the pharmacy partnered with.

The pharmacy dispensed prescriptions issued by an online prescribing service operated by another service provider. The prescribing service used pharmacist independent prescribers (PIP) to authorise the prescriptions. People wanting medicines were required to complete an online questionnaire to explain why they needed treatment. The PIPs then used the information from these questionnaires to decide whether to issue prescriptions. The SI also worked as a PIP for the online prescribing service. The prescribing service was not registered with the Care Quality Commission (CQC) or any other healthcare regulator and so it was not subject to inspection.

The SI explained that he had carried out some checks before he had started working with the prescribing service to satisfy himself that it was appropriate. He had visited the prescribing service's head office and met with its company directors and key members of the team so that he could understand what was expected of him. He had initially agreed to a four-week trial, following which the pharmacy continued the arrangement and it had been working with the prescribing service for around six months. The SI stated that the prescribing service did not offer medicines such as opioid pain-relief or z-drugs and it mostly prescribed erectile dysfunction treatments, some antibiotics and a range of lifestyle medicines. The pharmacy had dispensed nearly 47,000 prescriptions for the prescribing service in a six-month period which was a significant number. And the number of items had overtaken the number of NHS items it dispensed.

Standard operating procedures (SOP's) relating to the prescribing service were available. But they were not personalised to the pharmacy and they did not accurately reflect current practice. For example, one SOP referred to the online supply of over-the-counter medicines, including GSL and pharmacy (P) medicines, stating that the responsible pharmacist (RP) should review the online questionnaire and approve or reject the request. This was not the case as P medicines were supplied against private

prescriptions. Further SOPs relating to the prescribing service were provided following the inspection.

The SI explained that identity checking, patient interventions, patient specific counselling, contacting the patient's usual GP, and signposting were all completed by the prescribing service prior to the pharmacy receiving the prescription. But this appeared to be accepted by the pharmacy on trust. No records of these activities were kept at the pharmacy and there was no evidence available to provide assurance that they had taken place. Neither the SOPs nor the contract documents explained the process for contacting the patient's usual GP, or how counselling or messages were provided to the patient or who was responsible for this. There were no private prescription records available at the pharmacy. The SI explained that these were maintained by the prescribing service, which also held the original prescriptions and kept the prescribing records. This meant the pharmacy team did not have direct access to this information.

The pharmacy did not have any documented risk assessments relating to the online prescribing service that it had partnered with. This meant the SI was unable to show whether all of the risks associated with working with the service had been considered and mitigated. And so, the pharmacy could not provide assurance that the service was operating safely. For example, the responsible pharmacist (RP) could not easily access the answers to the online questionnaires that patients had completed. So, they could not satisfy themselves about the responses to the questionnaire or check whether the patient's usual doctor had been informed of the supply. And the pharmacy had not done any audits in relation to the prescribing service to identify potential prescribing issues or concerns.

Private prescription records were provided following the inspection, after being obtained from the prescribing service. The records were incomplete because prescription and dispensing dates were sometimes missing, and patient addresses did not always match those on the prescriptions. And the prescriber's address was not recorded. The records were reviewed, and many examples were found of people obtaining repeated supplies of medication, including medicines such as promethazine, which is known to be abused and misused. There were also examples of repeated supplies of antibiotics, medicines that required ongoing monitoring and medicines with a narrow margin of safety. The pharmacists relied on the prescribing service having checked that supplies were appropriate for the person requesting the medicine and making interventions or extra checks when necessary.

There was evidence that the prescribing service had repeatedly issued prescriptions for amitriptyline for a vulnerable patient. Two of these supplies had been made after the prescribing service had received a request from a GPhC investigations officer to not to make further supplies because of the risks involved. This demonstrated that the systems were flawed, and vulnerable people were not properly safeguarded.

Identity checks were apparently completed by the prescribing service for every patient, and this was explained in detail in the SOPs. The pharmacy could see that an identity check had been passed when they looked at the patient profile. The pharmacists could see details of previous prescriptions that the patient had received although it was unclear whether these included supplies made by other pharmacies, or just the ones that this pharmacy had supplied. And they could see a generic statement indicating the prescriber's justification for prescribing. The SI regularly worked as one of the prescribers for the service. He explained the justification for prescribing record was populated using a drop-down box with pre-written options for the prescriber to select.

The pharmacy had a current certificate of professional indemnity insurance on display. Responsible pharmacist (RP) logs were maintained in a record book and appeared to be complete.

Principle 2 - Staffing ✔ Not assessed

Summary findings

This principle was not assessed because the inspection focused on other key areas.

Inspector's evidence

The pharmacy separated its workload into two parts; NHS dispensing took place in the dispensary downstairs and the private prescription dispensing took place in a dispensary upstairs. Three dispensing assistants and the responsible pharmacist were working downstairs and two dispensing assistants were working upstairs. The SI was present, and the RP was a locum pharmacist who had worked at the pharmacy regularly on a part-time basis since mid-January 2022. The SI had completed a pharmacist independent prescribing qualification and had been registered as an independent prescriber since September 2015.

The pharmacy was paid for each prescription it dispensed on behalf of the online prescribing service, but it did not receive a payment if a prescription was rejected. The RP said that he had rejected a prescription as the expiry date of the medicine was not sufficient to cover the length of the supply. Prescriptions were reallocated to other pharmacies if they could not be dispensed.

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

Summary findings

The pharmacy is clean, tidy and provides a suitable environment for the delivery of healthcare services. The pharmacy works with an online prescribing service operating a website which is transactional in its approach and lets people choose the medicines they want before there has been an appropriate consultation with a prescriber. This means people may not always receive the most suitable treatment.

Inspector's evidence

The premises were smart in appearance and appeared to be well maintained. Various upgrades had been undertaken since the change of ownership, such as new lighting so that the customer area felt bright and welcoming. Large signs had been erected outside of the pharmacy to advertise the services that were available.

The online prescribing service used a website via which people could request prescription medication. The website was set out so that people could select the specific medicine they wanted before they started a consultation. The person could choose a particular medication, the strength and quantity they required, and then select ‘quick checkout’. The website did not contain the details of the pharmacy or pharmacies that supplied the prescriptions. And it did not contain the details of all of the pharmacist independent prescribers that issued the prescriptions for the service.

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

Summary findings

The pharmacy does not always carry out enough checks to make sure that medicines are safe and appropriate for the people it supplies. It cannot confirm whether the prescriptions it dispenses for the online prescribing service are meeting the legal requirements. And it cannot demonstrate that the online prescribing service shares information with a person's usual GP prior to a supply of a high-risk medicine being made to make sure their health and wellbeing is protected.

Inspector's evidence

People accessed the prescribing service directly via the service provider's website. They chose a medication and completed an online questionnaire. The questionnaire was reviewed by one of the pharmacist independent prescribers and if it was approved, a prescription was issued. The pharmacy team members could contact a clinical lead at the prescribing service if they had a question about prescription requests. The SI did not know what training the clinical leads had received.

PDF copies of prescriptions were emailed as a batch to the pharmacy to be dispensed. There were barcodes on each of the PDF's that allowed the pharmacy to cross reference the prescription to some additional information about the patient, such as previous dispensing history, and to update the progress of the order for the prescribing service and the patient. The PDFs were printed onto specially designed sheets of paper which contained the prescription details, the dispatch label and dispensing labels. It was unclear if the signature on the prescriptions met the requirements for an advanced electronic signature. The completed prescriptions were checked by one of the pharmacists, and then packaged for a courier to collect. There were a few different options for delivery and Royal Mail appeared to be the most popular. A PO Box address was included for returning undelivered medication but there was some confusion amongst the team about what happened to undelivered parcels. A dispenser thought that they were returned to the PO Box address, then collected by the prescribing service and delivered back to the pharmacy. The SOP did not go into any further detail about how undelivered medication was managed.

The pharmacy dispensed medicines in accordance with the prescriptions they received. The dispensing pharmacist carried out a basic clinical check of the prescription which was limited to whether the dose and strength of the medication prescribed were within the normal range for the patient. The pharmacy relied on the prescribing service to undertake all other checks but it did not seek evidence that these were being completed. And the pharmacy did not have evidence to show that the prescribing service was sharing relevant information about the medicines it prescribed with people's GP.

Principle 5 - Equipment and facilities ✔ Not assessed

Summary findings

This principle was not assessed because the inspection focused on other key areas.

Inspector's evidence

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.