General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: My London Pharmacy, 45 Newman Street, London, W1T 1QE

Pharmacy reference: 9011790

Type of pharmacy: Community

Date of inspection: 28/10/2022

Pharmacy context

This independent pharmacy first registered in February 2022. It occupies a retail premises in central London close to Tottenham Court Road tube station. It sells over the counter medicines, dispenses private prescriptions and offers covid testing services. Since the pharmacy first opened, it has developed an online service which people can access via its website www.mylondonpharmacy.com. It is also associated with another website www.chemist4now.com.uk. The pharmacy does not offer any NHS funded services.

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 has not adequately assessed the risks involved in providing its online prescribing service. It does not have appropriate policies and procedures in place to make sure it provides its services safely.
		1.2	Standard not met	The pharmacy has not reviewed or audited its prescribing service so it cannot provide assurance it is safe.
		1.6	Standard not met	The pharmacy cannot provide complete and accurate records to show how it prescribes and supplies medicines via its online services.
		1.8	Standard not met	The pharmacy does not have sufficient safeguards in place to make sure it protects vulnerable people seeking to purchase medicines online.
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 contains inappropriate and inaccurate information. And the layout allows people using the prescribing service to choose a medication before having a consultation with a prescriber.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy cannot provide assurance that its online prescribing service is operating safely. It does not take sufficient steps to verify the person's health status or confirm they are suitable to receive treatment, or make sure appropriate monitoring is in place.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

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

Summary findings

The pharmacy has not adequately assessed the risks involved in providing its online services. It does not have appropriate policies and procedures in place to make sure the team works effectively. And it has not reviewed or audited its prescribing service to make sure it is safe. The pharmacy team cannot provide complete and accurate records showing how it prescribes and supplies medicines. And it does not have proper systems in place to check people's identity when they request medicines online which is a safeguarding concern.

Inspector's evidence

The business was managed by two pharmacists who were both directors of the company which owned the pharmacy. One of the directors acted as the superintendent pharmacist (SI) and he worked most days at the pharmacy as the responsible pharmacist (RP). The company had initially used the premises to provide private covid testing services at the height of the pandemic, but later registered it as a pharmacy and expanded the business to provide pharmacy services. Covid PCR testing was still offered in partnership with a UKAS accredited laboratory. The pharmacy sold a small range of health and beauty products including some over the counter medicines and it dispensed a small number of walk-in private prescriptions each day. The main focus of the business was the online service which had been introduced some months after the pharmacy first registered.

The online service had been developed and set up by the SI. The pharmacy's website www.mylondon pharmacy.co.uk offered medicines to treat a range of conditions, including prescription only medicines and a few OTC medicines. Until recently, the pharmacy had operated a second website (www.chemist4now.com.uk) but this was no longer operational. People using the online service created and account and completed an online consultation questionnaire to request a treatment. Questionnaires were reviewed by the pharmacy's prescribers who issued an electronic prescription if a supply was authorised. The prescriptions were then dispensed and dispatched from the pharmacy. The pharmacy's online prescribers were two pharmacist independent prescribers (PIPs) who worked remotely. They used individual accounts to access the e-Consult system so they could view the questionnaires and issue prescriptions. The pharmacy mainly supplied Ozempic for weight loss and antibiotics for sexually transmitted diseases. Ozempic is not currently licensed for the weight loss in the UK, so this was prescribed for 'off-licence' use.

The pharmacy had copies of standard operating procedures (SOPs) that had been produced using commercially available templates. SOPs were not dated or signed by the SI or team members to show whether they had been implemented and were being followed. The SOPs focused mainly on dispensing processes, and they were not tailored to the pharmacy business. A simple flow chart outlined the online process but there were no SOPs specific to online activities explaining how this aspect of the service operated.

The SI explained some of the pharmacy's systems relating to online supplies and how these had been developed. But the pharmacy did not have any formal prescribing policies or clinical risk assessments for the online prescribing service identifying the therapeutic areas or medications that were prescribed regularly, showing how it managed these services safely or how it mitigated the risks associated with these medicines. And it had not completed any clinical audits to check systems were followed or identify any patterns or trends or areas of concern. This meant that the pharmacy could not be sure

their prescribers were following the most up-to-date guidance or evidence to support their prescribing. There was no prescribing guidance for prescribers to follow when prescribing. This meant there was a risk of inconsistent decisions being made by different prescribers involved in the service.

The SI explained the demand for Ozempic was considerable and the pharmacy had initially been supplying large amounts each week. But he had noticed some unusual requests and he felt that people did not always provide accurate information when completing questionnaires in order to make sure they obtained a supply of medicine. The pharmacy team were being more cautious when completing clinical checks made when supplying Ozempic, but the pharmacy had not introduced any additional safeguards such as extra checks to independently verify information provided on questionnaires. And there were also some ongoing issues obtaining Ozempic stock, which meant the volumes being supplied had recently reduced. The SI said the pharmacy was refusing more requests, but he could not provide any clear evidence to suport this.

The pharmacy's contact details and complaints procedure were included on the website. The SI handled any complaints and communicated with the person concerned. The pharmacy had procedures for recording near misses and patient safety incidents, and some near misses had been recorded.

The pharmacy had professional indemnity insurance provided by the National Pharmacy Association and the SI confirmed this cover included provision of online services. The pharmacy reimbursed the PIPs for the additional personal indemnity required relating to their work for the pharmacy's online prescribing service. An RP notice was displayed in the pharmacy and a log was maintained. But the log sometimes did not clearly identify the RP when two pharmacists were working at the same time. The pharmacy used a book to record walk in private prescriptions. It recorded online private prescriptions electronically, but the register could not viewed due to large number of entries. The SI provided copies of PDF excerpts from the register following the inspection when requested. But these were difficult to analyse and entries did not include the patient’s address. The pharmacy had only supplied one schedule 2 CD since opening and there was a CD register to show this medicine had been received and supplied. But the register contained loose leaf pages which do not meet legal requirements and could easily be removed or lost. The pharmacist viewed the online orders and prescriptions on the e-Consult system and recorded prescription supplies on a recognised PMR system. The pharmacist did not have access to clinical notes or consultation records, and it was not possible to access clinical records during the inspection.

The pharmacy was registered with the Information Commissioners Office. The website included the pharmacy's privacy policy. The website and payment systems were secure. Confidential material was stored so it was not visible to members of the public visiting the pharmacy. Confidential waste was disposed of safely. People using the pharmacy's services were required to complete a 'patient registration'. The pharmacy checked people's identity by asking them the upload their photo ID, such as a driving licence or passport, which provided proof they were aged over 18. But the pharmacy could not demonstrate whether this was consistently checked and some people did not provide photo ID. The SI described one person who had uploaded a photo rather than providing a copy of their photo ID, which meant the pharmacy had supplied the person without making further checks to confirm their age.

The SI was not able to explain how the pharmacy's online service protected people at risk of misusing the medicines they offered. Or people seeking medicines for sexual health inappropriately. There was no consistent way to refuse repeat requests which were deemed inappropriate. The pharmacy did not seek to verify health information provided on the questionnaires or use appropriate video consultations or other modes of consultation if these were needed as an additional safeguard.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy team is new and inexperienced. Team members receive some training for their roles, but the pharmacy does not have a structured approach to training or formal staff management systems to make sure team members develop the skills and expertise necessary for their roles.

Inspector's evidence

At the time of the inspection the only team members present were the two company directors. The team consisted of the two company directors who covered the RP duties, two PIPs and two support staff who worked in the pharmacy helping with general duties and dispensing. They were enrolled on accredited course and the SI provided confirmation of this. The pharmacy had a small customer service team who managed non-clinical queries and were home based. The SI explained that the support staff had been enrolled on accredited courses. But most of their training so far had been based on verbal instructions rather than formal training.

The SI stated that one of the PIPs specialised in weight loss but did not provide any evidence to support this claim. The pharmacy was in the process of recruiting two additional PIPs to support the prescribing service. PIPs were inducted by the SI. And the SI explained that he reviewed ongoing training completed by the PIPs but did not have any records of this. The service was set up to ensure clinical checks were completed by a separate person to the prescriber. But the pharmacy did not have routine access to the consultation notes from the prescriber or the responses to the online questionnaires. The SI could not outline any contingency arrangements if a prescriber was unwell and unable to work. There were no records of clinical supervision completed by the PIPs. This means that the pharmacy could provide assurance that the prescribers had the required knowledge to prescribe the range of medicines safely.

Staff signed contracts but the pharmacy did not have any other staff management systems such as performance reviews, a training and development programme, or a whistleblowing policy.

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

Summary findings

The pharmacy's website contains inappropriate and inaccurate information. And the layout allows people to choose a medication before having a consultation with the prescriber. This means there was a greater risk that people might not receive the most suitable treatment for their needs. The pharmacy premises are generally clean and secure. But the design and layout of the pharmacy could be improved to better accommodate the type of services it offers.

Inspector's evidence

The pharmacy occupied a small retail unit arranged over two floors. The ground floor included a small retail area, a dispensary and toilet. Stairs led to the basement which had an office or storage area, a staff kitchen and a toilet. The basement was due to be refurbished to include consultation facilities after a recent flood.

The pharmacy did not have a dedicated consultation room. Portable screens were used to provide some privacy for covid tests conducted on-site. The dispensary was basically fitted with shelving, and it had a small amount of bench space, and there was a small dispensary sink. Air conditioning controlled the room temperature. The dispensary was open plan and so the layout did not provide much privacy for the dispensing operation.

The pharmacy's website displayed some information about the pharmacy, and the pharmacy team including the prescribers. The website promoted Ozempic for weight loss which is outside the scope of its current marketing authorisation. And the website layout allowed people to choose prescription only medicines (POMs) before having a consultation, which means there was a greater risk that people might not receive the most suitable treatment option. Some of the website content was incorrect, for example the pharmacy's complaint procedure directed people to the GPhC but provided the wrong address details. And some of the website information referred to consultations with GMC-registered doctors which was misleading.

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

Summary findings

The pharmacy cannot demonstrate that its online prescribing service is operating safely. It supplies people with medicines without making sufficient checks to make sure the treatment is appropriate. And the pharmacy does not ensure people are monitored to make sure they are using medication correctly. Or routinely share information with the person's usual doctor or healthcare provider to support their ongoing care and wellbeing. The pharmacy sources and stores medicines appropriately. But it doesn't have a system in place to make sure it receives and actions drug or device alerts and recalls, so it cannot provide assurance that any defective medicines will be identified and removed.

Inspector's evidence

The pharmacy had a manual door at the entrance and access was reasonably unrestricted. The pharmacy was usually open 9.15am to 6.30pm Monday to Friday and 8.30am to 4.30pm on Saturday and Sunday. Staff could signpost to other services available locally including NHS and private providers. The pharmacy had established a working relationship a GMC registered doctor and a nurse prescriber who had initially acted as prescribers for the pharmacy's online service. The prescribing service was not registered with the Care Quality Commission. The pharmacy had recently decided to use PIPs for its prescribing service and it had stopped working with the other two prescribers in October 2022. Online services provided by the pharmacy were explained on the website and people could communicate with the pharmacy via telephone or email. The website included basic health information about the health conditions the pharmacy provided treatments for, but there was very little signposting information.

People created an account when requesting medicines via the website, but the system did not automatically highlight duplicate accounts or have any controls to prevent over ordering, so these checks had to be done manually. The pharmacy did not have a written policy explaining how frequently people could request medicines or how people were monitored. And there was no evidence of maximum quantities being applied to medicines selected by people using the website. The SI suggested the pharmacy operated a subscription service, but later confimred this was suspended pending further development.

The SI explained the pharmacy did not initiate Ozempic for weight loss and only provide ongoing treatment. People were asked for their weight and height which calculated their BMI and the questionnaire asked where they had obtained Ozempic previously and whether they had a recent review. But the pharmacy did not take any steps to verify this information or check whether the person had lost sufficient weight to enable treatment to continue. And the pharmacy did not routinely inform the clinic or healthcare professional who'd previously initiated treatment or inform the person's doctor of any treatment provided. This means people may be obtaining medicines from several sources without being monitored properly. The pharmacy could not demonstrate that the appropriate monitoring required for Ozempic was being completed after prescribing, so it could not provide assurance it was always being used safely.

The SI explained that prescribers used appropriate evidence-based guidelines for prescribing medicines for sexual health. But this was not documented in any formal policy or SOP. And it was not audited to check if prescribers were following the guidance appropriately. The SI provided examples of emails sent to people who had received medicines from the online service. These included information on the

condition being treated and reference to external patient information resources. But these were not in a template format or included in any protocol. So there was a risk that different prescribers could provide inconsistent information or only provide some patients with this information.

The SI provided online access to the e-consult system for inspectors to access remotely. A range of entries were reviewed following the inspection. Consultations for Ozempic did not contain details of prescribing rationale or reference to any guidance used to inform prescribing. There was no documentation of any verification of information provided by the person requesting the medicine. And there was no information about any monitoring or follow up needed. Key elements of the consultation form were not completed in some instances. Examples of omissions included passport numbers, patient contact details, diagnosis and advice provided. For one patient, co-amoxiclav was prescribed for acute sinusitis. This is a treatment option for people who are systemically unwell, but the consultation notes did not confirm this was the case. There was no documentation of how the prescriber assessed the severity of the infection and if the person was so unwell it was unclear the prescriber was satisfied they did not need to be seen in person. There was no record of advice being given about what the patient should do if they felt worse, were concerned about their symptoms, or if the treatment didn't resolve their symptoms. Another consultation was identified where two antibiotics (co-amoxiclav and azithromycin) had been prescribed for a chest infection. There was no rationale documented for this treatment choice and no indication whether any local or national guidance was being followed. It is not common for this treatment option to be selected for a chest infection, but the prescriber had not made any record to explain why they thought it was appropriate. And there was no record to show whether the prescriber had explored symptoms which may suggest a more serious condition. There was no record of advice being given to the patient about key symptoms to watch out for which may need in-person assessment. A female patient had been prescribed nitrofurantoin for five days to treat a urinary tract infection (UTI), but national guidance recommends a three-day course. The prescriber had not recorded their reasons for prescribing a longer course. And the symptoms documented did not indicate that a UTI was the only possible diagnosis.

Pharmacists usually assembled and checked prescription medication, sometimes with the help of support staff. The SI could not demonstrate that pharmacists had direct access to the consultation questionnaires or notes when assembling prescriptions so they could use this information to support their clinical check. Assembled online orders were dispatched using a Royal Mail service which could be tracked by the pharmacy. The pharmacy only supplied people based in the UK. Ozempic was placed in specialist cold chain packaging which had been validated by the manufacturer and maintained the temperature for 24 hours. Delivery was usually completed within this timeframe. The pharmacy had received some queries from people when packages were delivered but not handed to them directly meaning they were not refrigerated immediately. Ozempic was dispatched with a simple dispensing label as the pharmacy did not provide information about how to use it or how to dispose of needles. The SI said the customer service team emailed each person with this information and healthy eating advice once the medicine was dispatched, but he could not provide evidence of this.

The pharmacy supplied very few OTC medicines from the pharmacy or online. Sales were supervised by the pharmacist. The pharmacists were aware of OTC medicines which could be abused, and the pharmacy did not sell any codeine linctus or Phenergan Elixir as they knew they could be misused. The pharmacy dispensed less than 10 walk-in prescriptions each week. These were mostly issued by local doctors or clinics. The pharmacy occasionally received prescriptions written by EU doctors. It had recently supplied a private prescription issued by an EU prescriber without taking steps to verify its authenticity. The pharmacy did not have any valproate in stock, and it had not supplied any since opening. One of the pharmacists could not fully explain the risks of taking valproate and the pregnancy prevention programme, so there was a risk that people might not get the right information and

advice, if this medicine was required.

Covid testing was promoted via the website www.londontesting.co.uk. People could purchase PCR tests to do at home or they could elect to do the test in the pharmacy under supervision. Tests were collected by the lab and results were sent directly to the person.

The pharmacy sourced its medicines from licensed wholesalers. The SI explained Ozempic was in short supply, so the pharmacy had to send anonymised prescriptions to the manufacturers in order to obtain sufficient stock to fulfil the demand. More than 50 packs of Ozempic were stored in the dispensary fridge which was monitored to check the temperature was appropriate for the storage of medicines. Medicines were stored in an orderly manner on the dispensary shelves. Date checking systems had not yet been set up as the pharmacy was relatively new. The SI confimred a pharmaceutical waste contract had been arranged after the inspection. There was a small CD cabinet, but the pharmacy did not have any CDs requiring safe custody. The pharmacists were aware of the Yellow Card Scheme and had written to the doctors of three patients after they experienced side effects to Ozempic and they had reported these incidents to the MHRA. But the pharmacy did not routinely receive MHRA drug and device alerts and recalls, and neither pharmacists was aware of a recent alert relating to mebeverine.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services. Equipment is appropriately maintained and used in a way which protects people's privacy.

Inspector's evidence

The team could access the internet and appropriate reference sources. The pharmacy had cartons and packaging for assembling and dispatching medicines. The team used PPE when supporting people taking PCR tests. All electrical equipment appeared to be in working order. Computer systems were password protected.

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.