General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Medical Specialists, Westminster House, 49 Knowsley Street, BURY, Lancashire, BL9 0ST

Pharmacy reference: 1104466

Type of pharmacy: Internet / distance selling

Date of inspection: 28/05/2024

Pharmacy context

This private pharmacy provides its services to people through its website (https://www.medical-specialists.co.uk/). The website allows people to access the pharmacy's online prescribing service which offers prescription medicines for a wide range of conditions. The pharmacy mainly supplies medicines for the treatment of erectile dysfunction and menopause as well as medicines used for contraception and weight loss. People do not visit the pharmacy in person. The prescribing service is not registered with the Care Quality Commission (CQC).

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 adequately mitigate all of the risks associated with its prescribing service. Medicines are prescribed by relying solely on an online questionnaire. And there is no independent verification of the information people submit to help make sure that the treatments it provides are safe and appropriate.
		1.2	Standard not met	The pharmacy does not sufficiently monitor the safety and quality of its prescribing service. It doesn't analyse data from audits that it completes to identify learning and improvement opportunities.
		1.6	Standard not met	The pharmacy's consultation notes for its prescribing service do not always contain the relevant information. It does not record communication which has taken place between the PIP and the person receiving care.
2. Staff	Standards not all met	2.2	Standard not met	Prescribers do not complete adequate additional training for some of the specialist services provided.
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy advertises off-label medicines on its website which cannot be considered factual nor balanced because the medicines have not been assessed for quality, efficacy and safety for the indications they are advertised for.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not always obtain consent to communicate with a person's regular practitioner when using the prescribing service. And it does not take additional steps when prescribing for long term conditions or higher risk medicines to help make sure it is appropriate when consent is not obtained. Supplies of medicines for conditions which require ongoing monitoring are made without seeking sufficient assurances to ensure they are clinically suitable.
		4.3	Standard not met	The pharmacy does not have a robust procedure in place to deal with medicines

Principle	Principle finding	Exception standard reference	Notable practice	Why
				that have not been successfully delivered to people. Returned medicines are redelivered to people without any assurances that they have been stored in line with manufacturer's recommendations.
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 consider and mitigate all the of risks with its prescribing service. Medicines are generally prescribed by relying solely on an online questionnaire. And the pharmacy does not routinely use other sources to verify the information people provide it. Consent is not always sought to communicate with people's regular GP to ensure that the treatments it prescribes for people are safe and appropriate. Members of the team take appropriate steps to keep people's information safe and protect

Inspector's evidence

The pharmacy's main activity was the supply of prescription only medicines (POMs) against private prescriptions issued by its own prescribing service. The prescriptions were issued by three pharmacist independent prescribers (PIPs). The prescribing service only offered treatments to people aged over 18 years. The pharmacy's services were accessed via its website. People using the pharmacy's prescribing service completed an online consultation before a prescription was issued.

The pharmacy had a set of standard operating procedures (SOPs). Members of the pharmacy team had signed to say they had read and accepted the SOPs. Roles and responsibilities of the pharmacy team were described in individual SOPs. The correct RP notice was on display. Records for the RP and private prescriptions appeared to be in order. A current certificate of professional indemnity insurance was on display. All three prescribers had independent indemnity insurance.

The pharmacy had risk assessments which covered a range of conditions prescribing services were provided for. These included treatments for asthma, hormone replacement therapy (HRT), hair loss, migraine, diabetes, acne, urinary tract infections (UTI), dental infection, malaria, weight loss, emergency hormonal contraception (EHC), contraceptive pill, rosacea, hirsutism, eyelash regrowth and irritable bowel syndrome. The risk assessments took into consideration the prescribing activity. This included inclusion and exclusion criteria, cautions and whether any monitoring such as blood tests were required. The risk assessment also took into consideration when a person should be referred to the GP depending on if there were any concerns raised from the questionnaire or conversation with the person. As additional safeguards, the risk assessments also stated quantity limits. This was to ensure that people were not over ordering and to help the pharmacy supply a limited amount of the prescribed medicine over a defined period. Examples of order rejections were seen due to medicines being ordered too early. However, there was an allowance for 12 Ventolin inhalers over a 12-month period. The PIPs were unable to clinically justify the reason for such allowance when the national guidance suggests a person's asthma is uncontrolled if they are requesting a large volume of inhalers over a 12-month period without a valid clinical reason.

The pharmacy used a third-party identity (ID) checking system to confirm the identity of people using the prescribing services. This was completed when the person registered to use the service. The system also verified people's date of birth. If this failed, the pharmacy asked for evidence of a passport or driving license with proof of address. The director explained that there was a process to flag multiple accounts and evidence of the process was seen. The RP manually checked previous orders to identify repeat supplies of medicines to people. This was to help highlight if people were requesting medicines

to early or over ordering medicines inappropriately.

Before placing an order, people were required to complete an online questionnaire which covered key areas such as medical history and any risk factors that could stop the person from accessing the requested treatment. Questionnaires were reviewed by the PIP who issued an electronic private prescription if a supply was deemed appropriate. The PIPs explained they corresponded with people via telephone or email after they submitted the questionnaire if they needed additional information. And they documented this conversation on the internal record. However, this was not seen in majority of cases on the records looked at, so they were unable to demonstrate that this process was being followed.

It was observed from the records seen that people received treatment for which ongoing monitoring or management was needed. And the pharmacy had not taken steps to independently verify that the person had a confirmed diagnosis of the medical condition they were requesting the medicines for. For example, people received treatment for asthma and diabetes without adequate evidence that they had this condition. This meant there was risk of people receiving treatment that may not be appropriate, or safe, for them.

The superintendent pharmacist (SI) explained he audited prescriber's consultations by calling people to make sure the questionnaire responses matched the consultation. However, there was no learning identified from this. Audits were seen to have been completed at the pharmacy. However, nothing was done with the data and the results were not analysed. So, there was no subsequent learning identified or shared with the team. There were no audits carried out on the individual prescriber's prescriptions that they had generated. So, there was no analysis to see if prescribers where issuing prescriptions in line with guidelines which meant there was no opportunity to improve their prescribing practice.

Near misses were brought to team members attention and discussed. The office manager said there were not many near misses that had occurred. In the past, medicines had been separated on shelves. The responsible pharmacist (RP) was able to describe the process she would follow in the event that there was a dispensing error. She said there had not been any reported incidents. A pharmacist intervention log sheet was available, but this was blank, and the team could not recall anything being recorded.

People using the pharmacy's online service were required to provide consent to share information with their regular GP. This was only required for some of the conditions prescribed for. When consent was not sought or mandated, a risk-based discussion was not documented on the person's record to justify the prescribing decision. This was not in accordance with the regulatory guidance for pharmacies providing services at a distance. Records were seen to have a clear audit trail and showed which prescriber had added into the consultation notes. Private prescriptions had the names and identity of the prescriber for each prescription generated.

There was evidence of orders being rejected. For example an order for antibiotics was cancelled because the person had received a supply a few weeks before. People were also blocked from ordering medicines in some instances when it was not clinically appropriate. In these cases, a note was made on their record which was visible to the whole team in the event of a query.

The pharmacy had a complaints procedure which was explained on its website along with the contact details for the pharmacy. The pharmacy used Feefo to monitor customer service, and reviews could be seen on the website. People could also call and provide feedback or complaints to the customer services team.

An information governance (IG) policy was available, and the pharmacy team completed IG training every two years. Details about the pharmacy's cookies policy was detailed in the cookies and privacy policy on the website. Confidential waste was collected separately, and the pharmacy had a contract with a third party for destruction.

PIPs had completed safeguarding training as had the responsible pharmacist (RP). The pharmacy did not prescribe medicines for people under the age of 18. Details were available for local safeguarding boards. However, as the pharmacy supplied medicines to people nationwide, the office manager provided an assurance that he would look into the NHS safeguarding application.

Principle 2 - Staffing **Standards not all met**

Summary findings

The pharmacy has enough team members to manage its workload. Team members, including the prescribers, meet regularly and share learning on a regular basis. However, the prescribers do not always undertake adequate additional training for some of the specialist services they provide.

Inspector's evidence

The pharmacy team comprised of a customer services advisor, a dispensing assistant, who was also the office manager and a director, and another one of the directors of the company. A locum pharmacist was also present along with the RP. The PIPs mainly worked remotely. The SI, who was also one of the prescribers, was the regular RP but was on leave. On the days that the SI provided RP cover, he clinically checked prescriptions that he had generated which was not good practice. This meant there may not be an independent check to help make sure the medicines prescribed are safe and appropriate.

As part of the PIPs onboarding process, they confirmed they understood the SOPs, risk assessments and declared they had self-assessed themselves to be competent. The PIPs were experienced and worked in other roles within the NHS where they prescribed regularly. Training certificates were provided following the inspection to cover the range of clinical practice offered. However, there was limited evidence of training certificates to cover the prescribing for dental abscesses and the off-label prescribing of spironolactone and Lumigan. There was also no documented evidence of any peer reviews or testimonials for any of the PIPs. This meant that prescribers were potentially prescribing medicines that were not within their competence and the supplies may not always be appropriate for the person. Prescribers were paid for every consultation they reviewed. There was no evidence of the PIPs being incentivised to prescribe.

Staff performance was managed by one of the directors who held appraisals with team members every to 12 to 18 months. The SI discussed any issues directly with the prescribers. The SI explained they had regular meetings with the team and evidence was seen of the discussions that had taken place. For example, it was discussed that further information should be sought beyond the initial questionnaire with regards to weight loss medication requests. The PIPs met regularly and shared learnings on a regular basis. Examples were seen of a regular clinical governance meeting taking place. Team meetings were also held occasionally but as the team was small, issues and concerns were discussed as and when they arose.

Team members had completed training on health and safety, safeguarding and mental capacity. They had also been briefed on whistleblowing and slavery. There were no targets set for the services provided.

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

Summary findings

The pharmacy's website advertises off-label medicines which is not in line with the Medicines and Healthcare products Regulatory Agency's (MHRA) guidance. However, the pharmacy's premises are secure and suitable for the pharmacy's services.

Inspector's evidence

The pharmacy provided its services online through its website. This included a prescribing services and people could purchase over the counter medicines. The pharmacy's website advertised off-label use of medicines such as Lumigan eye drops and spironolactone which was not in line with the Medicines and Healthcare products Regulatory Agency's (MHRA) requirements. The pharmacy's website displayed the General Pharmaceutical Council (GPhC) voluntary logo. The website contained the required information, including the names of prescribers, the superintendent pharmacist, the responsible pharmacist and the address of the pharmacy from where the medicines were supplied as well as the contact details.

The dispensary was located on the top floor of the premises. Rooms on the other floors were used as storerooms and offices by the company's directors. The dispensary was clean and tidy, and appeared adequately maintained. The dispensary was spacious, and an appropriate size for the workload. The temperature and lighting were suitable. Members of the team had access to a kitchenette area and WC facilities.

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

Summary findings

The pharmacy does not always provide its services safely. It does not always seek sufficient assurances from people requesting medicines online to help make sure they are clinically appropriate. The pharmacy does not always obtain consent to communicate with a person's regular practitioner or take additional steps to ensure a medicine is appropriate when prescribing a higher-risk medicine or for a long-term health condition. So, there may be a chance of the pharmacy supplying medicines that are not safe for people. And it doesn't have a process for effectively managing failed deliveries. So, there is a risk that medicines that are not fit for purpose are supplied to people.

Inspector's evidence

People accessed the pharmacy's services via the website and could communicate with the team via telephone or email. There was also an option for people to be able to speak to the prescriber if needed.

Prescriptions were generated and sent electronically to the pharmacy once the online questionnaire was approved. The prescription was also linked to the messaging system so communication with people was visible to the pharmacy team members. And they were able to see the questionnaire responses. The services were advertised on the pharmacy's website and the pharmacy team were clear about what services were provided and when to refer people elsewhere.

People requesting antibiotics, Lumigan or spironolactone needed to provide consent for the prescribing service to share information with their regular GP. However, this was not the case for other conditions including some higher-risk medicines and medicines which required ongoing monitoring. This meant the pharmacy did not have assurances that the treatment was being appropriately monitored. People's regular GPs were contacted via post. A cover letter was sent along with a copy of the consultation. In some cases, the pharmacy received responses back from the surgery informing them that the patient was not registered. In this case a team member would contact the patient asking them to provide current details.

In most cases, the pharmacy relied on people's answers to an online questionnaire before prescribing a medicine. Negative responses were not highlighted to people as they completed the questionnaire. So, people were not able to change their initial answers to obtain medicines that were not suitable for them. However, it did not always independently verify people's medical history when prescribing higher-risk medicines.

The information from the questionnaire covered the key points to help inform the PIP before making a prescribing decision. Completed questionnaires were reviewed by a PIP before a decision was made if the person was suitable for the treatment. If the person qualified for the treatment, the PIP sometimes contacted people via telephone or email. The PIPs explained they documented the full consultation on the internal record however this was not seen in majority of cases. PIPs used their own professional judgement when prescribing. Examples were seen where orders had been rejected such as a person requesting HRT which was not appropriate.

Some medicines that were supplied by the pharmacy could not be initiated by the prescribing service as the person needed a confirmed diagnosis of the condition and been previously prescribed the medicine.

An example of this was Ventolin or metformin. However, the pharmacy did not consistently verify that these conditions were being monitored or whether the person requesting the medicines had a previous diagnosis. This meant that the prescribing of these medicines may not always be appropriate.

The pharmacy prescribed some medicines for off label use. These included spironolactone for hirsutism and Lumigan for eye lash growth. The PIPs explained they requested blood tests and pictures to seek evidence of hirsutism. However, they did not verify the medical history of the patient. There was evidence that a person submitted the same photo to receive a supply of the medicine they requested. This meant the pharmacy was unable to demonstrate they adequately verified information that people provided to them. People were prescribed Lumigan for eye lash growth using a questionnaire-based model, but the medical information was not independently verified. Although people were provided with an information leaflet, they were not adequately counselled on the risks associated with its use which meant people were at risk of developing eye symptoms using a medicine which was licensed for managing glaucoma.

Prescribers were able to see people's historical orders and supplies on the computer system. And they used evidence-based guidelines and local formularies to help inform prescribing decisions for most conditions. Evidence was seen of orders being put on hold when a supply had been deemed inappropriate. Antibiotics were prescribed and dispensed for dental infections. The pharmacy had a restriction on the number of antibiotics that could be prescribed over a defined period. However, people were at risk of inappropriately receiving antibiotics for dental infections as prescribers were solely relying on a questionnaire to assess symptoms.

Once prescriptions had been issued, they were printed out in the dispensary, and dispensed by one of the dispensers. The RP completed the clinical and accuracy check of the prescriptions. Checked prescriptions were packaged and prepared, ready to be collected by the courier service. The dispensary shelves were well organised and tidy. 'Dispensed-by' and 'checked-by' boxes were initialled on the dispensing labels to provide an audit trail. Baskets were used to prevent prescriptions becoming mixed up. People were supplied with patient information leaflets containing information about their medicines.

Medicines were delivered to people by courier and all deliveries were sent on a tracked service. Medicines requiring refrigeration, were sent in a special container, to maintain the correct temperature during delivery. The pharmacy team had not carried out any checks to ensure the packaging was effective. The office manager and director explained that they had contacted the manufacturers of the packaging who had assured them that the packaging would maintain temperatures over a 48-hour period. However, there was no documentation or certificates with this information.

The pharmacy did not have an adequate process to effectively manage failed deliveries. And there wasn't a specified number of reattempts the courier company would make. Once failed packages were received by the pharmacy, people were notified by email and a record was made on a spreadsheet. The package was left for 90 days, and delivery was reattempted within this period if they contacted the pharmacy team. The pharmacy had no assurances that conditions the medicine had been stored under by the courier company before it was returned to the pharmacy were appropriate. So, there was a chance that people are supplied with medicines that are not fit for purpose.

The pharmacy also sold over-the-counter medicines from the website. The questionnaires for these requests were like the online consultation for POMs. The questionnaires were reviewed by the RP who contacted people for more information if needed.

Medicines were obtained from licensed wholesalers. Stock was date checked every three months. A

date checking matrix was signed by team members to show what had been checked. A controlled drugs cabinet was available, but it did not contain any stock. There was a clean fridge, equipped with a thermometer. The minimum and maximum temperatures were recorded daily and had remained in the required range required for the storage of cold chain medicines. Patient returned medication was disposed of in designated bins. Drug alerts were received by email from the MHRA and were forwarded onto the SI who dealt with them, the pharmacy held a small range of medicines.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs for its services. Its team members use the equipment in a way to help protect people's private information.

Inspector's evidence

Team members had access to the internet for general information. The pharmacy had counting triangles for counting loose tablets. Equipment was kept clean. Computers were password protected. A fridge was available. The pharmacy also had a CD cabinet which was no longer used. A cordless phone was available in the pharmacy which allowed team members to move to a private area if the phone call warranted privacy. As the pharmacy was closed to the public this helped to protect people's confidentiality. An in-house IT system was used, and IT support was available at a distance.

Confirmation was given that IT met the latest security specification. Computers and the patient medication records (PMR) were password protected and passwords were changed frequently.

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.