General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Healthcare and Aesthetic Pharmacy, 1 Guest

Street, Leigh, Greater Manchester, WN7 2RP

Pharmacy reference: 9011857

Type of pharmacy: Internet / distance selling

Date of inspection: 14/04/2023

Pharmacy context

This pharmacy is closed to the public, and it primarily provides dispensing services directly to healthcare prescribers or aesthetic practitioners. It is located in a small unit within an office building, in the town of Leigh, Greater Manchester. The pharmacy does not have an NHS contract, instead it specialises in supplying non-surgical cosmetic and aesthetic products, and consumables against private prescriptions generated by prescribers through its website www.refinepharma.com. It also dispenses a limited range of antibiotics and medicines used to aid weight loss.

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 is not able to demonstrate that it has risk-assessed all of its services or show how it manages the risks associated with a prescribing service that is not registered with a UK regulator.
		1.6	Standard not met	The pharmacy does not keep appropriate records of the medicines it supplies against private prescriptions.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy is associated with a website which enables people to select a medicine before starting a consultation.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy is associated with various prescribers, but it does not know how all of their services operate so it cannot provide assurance that they are prescribing safely. And it does not always have enough information to provide assurance that the medicines it supplies are being used appropriately.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

Members of the pharmacy team follow written procedures to help them work effectively. They record things that go wrong and discuss them to help identify learning and reduce the chances of similar mistakes happening again. But the pharmacy does not keep a record of private prescriptions it dispenses, as required by law. And it is not able to demonstrate that it has risk-assessed all of its services or show how it manages the risks associated with working with a prescribing service that is not registered with a UK regulator. So the pharmacy cannot provide assurance that the medicines it supplies are always safe and appropriate for the people who receive them.

Inspector's evidence

The pharmacy first started operating a few years ago from a premises in Liverpool, and due to business growth, it relocated to these premises in 2022. The pharmacy provides services through its website www.refinepharma.com. A range of medicines used in non-surgical cosmetic treatments were supplied against electronic prescriptions written by UK prescribers. Practitioners could also purchase non-prescription items directly from the website, such as dermal fillers, and injectable consumables. Anyone wishing to use the website was required to register an account and go through an 'on-boarding' process for approval. They were not able to place orders through the website until the account had been approved. If the account holder ordered a medicine that required a prescription, the website could be used to generate an electronic prescription and then a prescriber linked to their account could 'approve' it. Alternatively, the person could authorise the prescription themselves if they had prescriber rights. The orders would then be supplied by the pharmacy and sent via courier.

The on-boarding process to create accounts involved checking a person's identity against a passport photo or driving licence, their professional registration status, evidence of training, and their certificate of insurance. And following the on-boarding process there were random checks of the prescriber's professional registration and insurance. But the pharmacy did not routinely check the registration upon receipt of a prescription. This meant the pharmacy may not always have up to date information about the current registration status of prescribers at the time prescriptions were dispensed. So they may not be aware if prescriptions were issued by people who were no longer entitled to prescribe.

Only a pharmacist or the operations manager were permitted to approve an account. The insurance checks also included checking which areas the practitioner was covered to inject, and then comparing against the first prescription generated by their prescriber to confirm they were working within their insurance cover. But there were no subsequent restrictions on the products they could obtain from the website, and no further checks completed. This meant the pharmacy could not provide assurance that subsequent prescriptions supplied were for treatments that were covered by the practitioner's insurance.

Prescribers were treated as individuals, and the pharmacy had not considered the implications of organisations using the pharmacy's systems to generate prescriptions. For example, the pharmacy dispensed prescriptions for a weight-loss service in which medicines were prescribed by nurses. But the pharmacy had not checked whether this service required registration with CQC. And most of the medicines being prescribed by the service were off-label and not being used for their licensed indications. But the pharmacy had not taken any steps to provide assurance that the prescriptions were

appropriate.

The pharmacy had a set of standard operating procedures (SOPs) which were in the process of being updated and stored electronically. Members of the pharmacy team had signed training sheets to say they had read and accepted the SOPs. .

The pharmacy had completed risk assessments for the medicines it dispensed. But it was not clear who had completed the risk assessments or whether they had been agreed by the superintendent pharmacist (SI). And some of the information within the risk-assessment appeared to be inaccurate. For example, the risk-assessment stipulated that the maximum allowable quantity of Botox on prescription was equivalent to 500iu every 3 months. But the product license of Botox recommends the maximum dose for all indications is 400iu within a 12-week period. The pharmacy had not completed risk assessments covering its services and activities. So the pharmacy cannot demonstrate it has identified and mitigated all of the risks associated with its services.

The pharmacy had systems in place to identify and manage risk, such as records of dispensing errors and their learning outcomes. Near miss incidents were recorded on a paper log. The pharmacist reviewed the records each month and discussed any learning points with members of the team. The team had taken action to help prevent similar mistakes being repeated. For example, by moving some medicines away from one another in the dispensary and instructing team members to mark packaging as an additional checking step.

Members of the team kept a record of any interventions they had made before supplying prescribed medicines, and any subsequent outcome. For example, the pharmacist had contacted the prescriber on one occasion due to a repeat prescription for Botox within a few days of the first prescription. The prescriber had explained that it was to be injected in a different area of the body.

Roles and responsibilities of the pharmacy team were described within SOPs. A dispenser was able to explain what her responsibilities were and was clear about the tasks which could or could not be conducted during the absence of a pharmacist. The responsible pharmacist (RP) had their notice displayed prominently. The pharmacy had a complaints procedure, and this was displayed on the website. A current certificate of professional indemnity insurance was available.

Records for the RP appeared to be in order. But the pharmacy did not have a private prescription register. And the electronic software it used did not have functionality to generate a report which met the requirements of a private prescription register.

Information governance (IG) procedures had been implemented. And details about how the pharmacy used and protected people's information was displayed in a privacy policy on the website. A shredder was used to destroy any confidential information. Members of the team understood the need to protect people's information, but they had not completed any formal data protection training. So they may not always fully understand their responsibilities. Safeguarding procedures were included in the SOPs and the pharmacy team had completed safeguarding training. The pharmacist had completed level 2 safeguarding training. Members of the team said they would refer any initial concerns about people's safety to the pharmacist on duty.

Principle 2 - Staffing ✓ Standards met

Summary findings

There are enough staff to manage the pharmacy's workload. Members of the pharmacy team complete some training to help them understand the services being provided.

Inspector's evidence

The pharmacy team included two pharmacists, one of whom was the SI, a trainee pharmacy technician, and two dispensers. There was also a customer services team who did not work within the pharmacy. All members of the pharmacy team were appropriately trained. The pharmacist would usually be supported by one or two dispensers and the volume of work appeared to be managed. Staffing levels were maintained by part-time staff and a staggered holiday system.

The SI was a trained aesthetician. To help provide members of the team with a greater understanding of the products being supplied by the pharmacy, the SI had created a series of training videos. The videos explained the different types of products supplied and the associated consumables. RPs were given the risk assessments and shown the training videos to help them to understand the products being supplied.

A training folder contained records of additional training members of the team completed. Training topics appeared relevant to the services provided and those completing the e-learning. Team members were allowed learning time to complete training. A dispenser said she did not directly speak to prescribers or patients about their medicines, and any medication queries would be referred to the pharmacist to answer. Members of the team said they felt a good level of support from the pharmacists. Appraisals were conducted annually by the SI. A dispenser said she felt the process was fair and was able to speak about any of her own concerns. Team members were aware of the whistleblowing policy and said that they would be comfortable reporting any concerns to the SI. There were no professional targets in place.

Principle 3 - Premises Standards not all met

Summary findings

The pharmacy premises are suitable for the services provided. And the pharmacy's website displays enough information for people to know who is providing the service. But the pharmacy works with a weight loss service whose website allows people to select a medicine before a consultation. So there is more risk that people may not receive the most appropriate treatment for their needs.

Inspector's evidence

The pharmacy was located in a unit inside an office block. The premises were clean and tidy, and appeared adequately maintained. The size of the dispensary was sufficient for the workload and access to it was restricted by a lockable door. The temperature was controlled using air conditioning units. Lighting was sufficient. Team members had access to a kitchenette and WC facilities.

The pharmacy website contained information about where the pharmacy was located, who owned it and the SI. It also contained details about how to check the registration status of the pharmacy or SI. The pharmacy dispensed prescriptions on behalf of a weight loss service which operated via the website www.slimmerssucess.co.uk. This website was set out so that people could select a medicine before starting a consultation.

Principle 4 - Services Standards not all met

Summary findings

The pharmacy is associated with various prescribers, including some that provide a weight-loss service, and dispenses the prescriptions they issue. But it does not know how all of the prescribing services operate so it cannot provide assurance that they are prescribing safely. And it does not always have enough information to provide assurance that the medicines it supplies are being used appropriately.

Inspector's evidence

People who used the pharmacy's services accessed them through its website. The website had various help sections to provide support. It also included details about how to contact the pharmacy, the hours of opening, and how to contact team members when the pharmacy was closed.

Electronic prescriptions could be issued via the pharmacy website. When a prescription medicine was requested, a dispenser printed a paper 'token' of the electronic prescription and wrote on the token additional information, such as whether the patient was new, or the dates of any previous orders for the same medicines. Prescriber were required to complete checkboxes when they issued prescriptions to provide assurance to the pharmacy. For example, indicating the consultation had been completed face-to-face, details of the patient's allergies, confirmation that any monitoring requirements had been completed and that the medication was to be used by the named patient.

The pharmacy dispensed prescriptions for weight-loss treatments issued by nurse prescribers for the 'Slimmer's Success' service. The SI was not able to explain how the service was provided. He did not know whether the prescribers had a reliable method to confirm the patient's weight. And he did not know whether consultations were completed face-to-face or remotely. There was no formal agreement between the pharmacy and the weight loss service The pharmacy dispensed a large number of prescriptions for the service, but the SI said the prescribers were able to send prescriptions elsewhere. The address for Slimmer's Success was listed on Google as the same office block as the pharmacy.

The pharmacy team initialled dispensed by and checked by boxes on dispensing labels to provide an audit trail. They used dispensing baskets to separate individual patients' prescriptions to avoid items being mixed up.

Medicines were delivered using courier services. Electronic records of deliveries were retained. Any unsuccessful deliveries were returned to the pharmacy and the pharmacist would contact the customer to check why the medicines could not be delivered. Medicines requiring refrigeration were sent using special packaging to keep the medicines within the required storage temperatures. The pharmacy had carried out testing to check the packaging worked as expected during hot summer months and colder winter months.

Medicines were obtained from licensed wholesalers, and any unlicensed medicines were sourced from a specials manufacturer. Stock was date checked at least once every three months. Records of date checking were available. Short-dated stock was highlighted using a sticker and recorded in a diary for it to be removed at the start of the month of expiry. There were clean medicines fridges, each equipped with a thermometer. The minimum and maximum temperatures were being recorded daily and records showed they had remained within the required range for the last 3 months. Patient returned

medication was disposed of in designated bins. Drug alerts were received by email from the MHRA. Alerts were printed, action taken was written on, initialled and signed before being filed in a folder. In the event of an adverse reaction, the pharmacy was a member of the 'Aesthetics complication expert' group, which had written protocols to manage patient safety incidents.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

Members of the pharmacy team have access to the equipment they need for the services they provide.

Inspector's evidence

The team members had access to the internet for general information. All electrical equipment appeared to be in working order. Computers 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.	