General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Phlo-Digital Pharmacy, Unit 1, Fifth Street, Trafford Park, Manchester, Greater Manchester, M17 1JX

Pharmacy reference: 9011171

Type of pharmacy: Internet / distance selling

Date of inspection: 18/07/2024

Pharmacy context

This pharmacy is situated in a business park. It operates a distance-selling service, so people do not visit it in person. This inspection primarily focussed on the pharmacy's online weight-loss treatment service which it introduced around March 2024. The pharmacy has its own website www.phloclinic.co.uk where people can register for the weight-loss service. The pharmacy offers medicines for other conditions on its website, as well as prescribing and supplying injectable weight loss medications.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy manages its risks reasonably well. The prescribing team has written instructions to help make sure it provides a safe weight-loss service. The prescribing and pharmacy teams discuss their mistakes which helps them to learn from them. The pharmacy protects people's private information, and team members understand their role in protecting and supporting vulnerable people. The pharmacy keeps consultation records for people when it prescribes weight loss medicines. But records generally do not have enough detailed information needed to clearly explain the clinical reasons for authorising supplies.

Inspector's evidence

The terms and condition section of the pharmacy's website stated that the pharmacy owner employed a UK registered General Practitioner as the medical director who oversaw the prescribing team. People could contact the medical director via the pharmacy. The prescribing service was not registered with the Care Quality Commission (CQC). The superintendent pharmacist was based at the pharmacy. The chief operating officer, who had strategic oversight across the weight-loss service provision alongside the prescribers and pharmacy, periodically visited the pharmacy. The pharmacy team reported to the head of pharmacy operations, who was a pharmacist, visited the pharmacy each week and attended interdepartmental meetings. The head of patient care, who was a pharmacist based at the pharmacy owner's head office, liaised between patients, prescribers and the pharmacy team to facilitate safe and effective communication.

The pharmacy's prescribers were all pharmacist independent prescribers who were directly employed. The pharmacy mainly prescribed and supplied the GLP-1 receptor agonist weight-loss treatments tirzepatide (Mounjaro) and semaglutide (Wegovy) injections for UK residents.

The prescribers and pharmacists working in the pharmacy team followed guidelines for weight management treatments in adults (weight management guidelines) that the superintendent pharmacist had co-authored with the chief pharmacist and two of the prescribers. These guidelines referenced the General Medical Council's guidance on remote prescribing principles, and manufacturer's information on tirzepatide and semaglutide injections. They included exclusion criteria, how to clinically review new patients, and monitoring of existing patients. This framework helped to make sure prescribers only recommended weight loss treatments to people who were suitable for treatment. The weight management guidelines stated that when deciding if a treatment was appropriate, prescribers must check people's medical records (NHS National Care Records NCR) to confirm the completeness and accuracy of information reported in the online questionnaire. This included requesting body and weighing scale images from people to confirm their weight. The superintendent pharmacist explained that the prescriber completed additional enquiries if the weight recorded in people's medical history was more than eighteen months old. However, the eighteen-month time limit was not specified in the weight management guidelines, so additional checks might not always happen.

The pharmacy's prescribers verified people's age, identity, and email address via the NHS Digital Personal Demographic Service (PDS) and a private external online identity checking service. Prescribers additionally checked people's details on their NCR.

The chief operating officer liaised with the technical team about the weight-loss service's IT systems.

The superintendent explained that he, the chief operating officer and the head of pharmacy operations met representatives from the manufacturers of tirzepatide injections every two weeks. These meetings included sharing the latest clinical and operational data. This information was used to provide training updates to the prescribers.

The weight-loss service had various clinical governance oversight arrangements to help support patient safety. The prescribers audited each other's prescribing each month. The prescribing team met weekly to discuss any significant incidents and emerging trends. The prescribing and pharmacy teams had written procedures for reporting and analysing prescribing and dispensing mistakes. Additionally, the medical director, superintendent, chief operating officer, and prescribers met monthly to review clinical near misses that the pharmacy had detected when preparing prescription medicines. The medical director, superintendent chief operating officer, two of the prescribers and external primary care doctors, who acted as consultants, attended quarterly advisory board meetings. The group regularly reviewed completed risk assessments and the prescriber's weight management guidelines.

The pharmacy team had written procedures that covered safe dispensing and supply of prescription medications. It kept an audit trail on the electronic patient medication record system (PMR) to identify who prepared and checked each prescription medication. This helped to clarify who was responsible for each prescription medication they supplied. And this assisted with investigating and managing mistakes.

The terms and conditions section on the pharmacy's website explained how people could make a complaint. People had occasionally contacted the pharmacy to suggest that they had received a faulty weight-loss injection. The pharmacy arranged for these injections to be sent to the manufacturer, who investigated for any issues. The manufacturer had frequently reported that there wasn't a fault with the injection but that the person needed support with the injecting technique. To mitigate this from happening, the superintendent pharmacist explained that when the pharmacy first supplied a patient it emailed them images and a link to videos that showed how to use the injection. The pharmacy additionally provided its own leaflet to patients that explained how to use the tirzepatide injection, which included frequently asked questions. These arrangements meant the pharmacy rarely received queries from people on how to use the injection.

The pharmacy had received a small number of complaints from patients regarding cosmetic damage to weight-loss injection packaging such as an ice pack that had leaked. But the injections remained useable, and the pharmacy assured people about this.

The pharmacy had prescribing records for each person who requested treatment. The records included a basic audit trail that specified the prescriber who had verified the patient's identity, the additional information they had requested from the person such as body images that confirmed their weight, that they had reviewed each treatment request and their prescribing decision, the date of their decision, and the weight-loss treatment prescribed. However, the records did not clearly demonstrate when the prescriber had identified people who were not suitable for weight-loss treatments, or that they had clinically reviewed the person's online questionnaire responses and medical record (NCR), verified the person's height and weight when they requested treatment for the first time, or properly evaluated subsequent requests from existing patients to continue treatment. Also, the records did not include communications with the patient during the initial consultation phase. This meant the pharmacy could not easily explain the clinical reasons for authorising supplies as the records did not have enough detailed information.

The pharmacy had professional indemnity insurance cover for the services it provided. The responsible pharmacist (RP) displayed their RP notice so the public could identify them. The pharmacy kept records of the RP in charge of the pharmacy.

The prescribers submitted electronic weight-loss injection prescriptions to the pharmacy that included their unique identifier code, the patient's name, address, and prescribing date. The pharmacy kept an electronic patient medication record (PMR) for each person it supplied. It maintained a private prescription register for weight-loss prescription supplies as required by law. Register entries included the prescriber's details, prescribing date, patient's details, medication, supply date, and reference number to aid retrieving the corresponding prescription.

The pharmacy was registered with the Information Commissioner's Office. It displayed information about its privacy policy on the pharmacy's website, so people could find out how it protected their data. The pharmacy had processes for dealing with potential data breaches.

Prescribers and pharmacy team members had completed data protection training. The pharmacy requested people's consent to view their NCR or GP medical record and share information with their GP. The prescribers securely accessed people's electronic prescribing record, which helped protect people's records from unauthorised entry. Only authorised pharmacy team members had access to people's electronic prescriptions.

People were asked whether they had specific mental health conditions such as any eating disorders, psychosis, depression, anxiety, or bipolar illness when they completed the online questionnaire for the weight-loss treatment service. However, the online questionnaire advised people that some weight-loss treatments may not be suitable in some mental health conditions prior to them submitting their responses. This may lead to people providing misleading responses to obtain a treatment. The pharmacy took steps to verify this information that people had provided by accessing their NCR, or contacting their GP.

The prescribers and pharmacists working in the pharmacy team had level two or three safeguarding accreditation. The weight management guidelines indicated that prescribers must not prescribe if there was any history of an eating disorder, and they highlighted the potential misuse of weight management products, including when people provided inaccurate information about their height, weight, or medical history during the screening process. The guidelines emphasised that the prescriber understands the misuse potential of weight-loss treatments and implements strategies to verify patient-reported information through cross-referencing their clinical records and requesting photographic evidence where necessary.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to provide its services safely. The team members work well together. New team members receive the appropriate training for their roles and the pharmacy effectively supports them to complete this. The pharmacy regularly reviews the performance and development of its prescribers to make sure they have the right skills and knowledge.

Inspector's evidence

All the prescribers worked remotely from the pharmacy premises. The medical director appraised each prescriber's performance and development needs annually using CQC guidance for reference. As part of the recruitment process, the medical director assessed each prescriber's competency via a series of test medication requests.

One of the senior prescribers completed weight-loss training under the supervision of a consultant, who was a GP, before the pharmacy started the weight-loss service. The consultant and senior prescriber subsequently designed a training plan to prepare the other prescribers to provide the weight-loss service.

The pharmacy had introduced a framework of peer support and clinical oversight for the junior prescribers. This included a weekly individual session with a senior prescriber to review their performance and provide guidance, and a minimum of six shadowing sessions during their induction period where each junior prescriber directly observed senior prescriber consultations. Junior and senior prescribers escalated complex cases for group discussion when necessary.

The prescribing team maintained a prompt service. The pharmacy team had enough staff to comfortably manage its workload. The team working in the pharmacy consisted of two pharmacists, an Accredited Checking Technician (ACT) who was the pharmacy manager, four dispensers, a trainee dispenser and five team members who exclusively packed medications for dispatch. All prescription medicines were ready for dispatch by 5pm against prescriptions received the same day. The prescribing and pharmacy teams did not have any targets for the volume of services they provided.

The pharmacy team members worked well both independently and collectively. They used their initiative to manage their assigned roles and they did not need constant supervision. The trainee dispenser, who started working at the pharmacy around May 2024, had been enrolled on an appropriate dispensing qualification course. Their training was progressing well, and they were receiving the support necessary to keep developing their skills and knowledge. The five team members working on packaging medicines for dispatch had completed or were completing bespoke training for this role.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean, secure, and spacious enough for the pharmacy's services. And the pharmacy provides a professional environment for the delivery of healthcare services. The pharmacy's website contains information about the pharmacy and the associated weight-loss treatment service.

Inspector's evidence

The pharmacy was situated inside a warehouse unit. Its dispensary and office were suitably maintained, and it was professional in appearance. The open-plan dispensary area included separate sections to prepare, check, pack and dispatch medicines. It provided enough space for the volume and nature of the pharmacy's services. A consultation room was not necessary because people did not visit the premises. The level of cleanliness was appropriate for the services provided. Staff could secure the premises to prevent unauthorised access.

The pharmacy’s website included its premises address and contact telephone number, the superintendent pharmacist’s details, links to check the registration status of the premises and superintendent, and the owner’s address. The website also displayed two of the three pharmacist prescribers' identities, their role, registration numbers, and a link so that people could check their registration status.

The pharmacy’s website offered a range of weight-loss treatments. People first requested a weight-loss consultation, which led to an online questionnaire on the website. Before submitting their responses to the online questionnaire, people were presented with the potential treatment options that the prescriber may approve if the person was assessed as suitable to receive treatment.

The pharmacy used social media to promote its services, which the superintendent pharmacist oversaw. This included making sure the pharmacy adhered to advertising regulations. He agreed to monitor the weight-loss service’s social media accounts with the marketing department to make sure the pharmacy did not promote any prescription only medicines (POMs).

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy obtains and verifies information provided by people requesting weight loss medicines, to help prescribers assess whether a weight-loss treatment is suitable for them. It provides relevant advice and support to help make sure people use these treatments safely. The pharmacy gets its medicines from licensed suppliers. It makes sure they are in good condition and suitable to supply.

Inspector's evidence

The pharmacy operated 8am to 6pm Monday to Friday. People completed an online questionnaire to confirm their age, gender, healthcare status including any existing medical conditions. They were asked for their height and weight, which automatically calculated their Body Mass Index (BMI), and whether they had tried any weight loss treatment before. The questionnaire informed people of their eligibility for weight-loss treatment before they had submitted any of their responses. It also informed people prior to submission that, if they stated that they had previously received a weight-loss treatment from another service provider, they were unlikely to receive a treatment. And the system did not track or record people's changed answers on the questionnaire. So, people could alter their responses prior to submission to increase the likelihood of them receiving a treatment. The pharmacy used software to detect any body images that people had submitted to falsely verify their BMI.

The prescribers asked people resident in Scotland and Wales for access to their GP medical record, because there was no equivalent of the NCR. People not registered with the NHS or a GP were asked to produce their medical records.

The weight management guidelines required prescribers to clinically review people's medical records to verify information from the person requesting treatment and identify anyone who must not be prescribed weight-loss treatments. The guidelines also advised prescribers to clinically review people's medical history for weight-related conditions that may suggest a treatment was appropriate.

The pharmacy's prescribers issued electronic weight-loss injection prescriptions that included appropriate directions to inject as directed, once weekly on the same day. People who completed the online weight-loss questionnaire needed to confirm that they would read the patient information leaflet provided and follow the appropriate storage instructions for weight-loss injections. The pharmacy provided relevant advice to people and signposted them to healthcare professionals when it supplied weight-loss injections. The superintendent pharmacist explained that the pharmacy emailed patients healthy diet, physical activity and contraceptive advice. The email advised people to report any concerns or serious side-effects, and to stop taking the medication if they experience symptoms associated with pancreatitis or a sustained increased heart rate. The email included the prescribers and a dietician's contact details who were available to help people manage their weight-loss. The weight management guidelines did not clarify who was responsible for sending this information to the patient.

The superintendent pharmacist explained that the pharmacy owner's patient services team, which was pharmacist-led, triaged any clinical and product supply related issues that people reported. Clinical and product issues were sent to the head of patient care and pharmacy respectively. Any subsequent telephone conversations with the patient were recorded and notes of these discussions were entered on their prescribing record. The weight management guidelines referenced informing the MHRA about any adverse reactions to injections that people reported.

People completed the online questionnaire for each repeat treatment request. The weight management guidelines advised prescribers on points to consider when reviewing prescription requests for a maintenance or increased dose of an approved treatment. This included to re-titrate people's injection dose if the patient had a gap of four or more weeks in treatment, and reducing or stopping medication if they reported excessive weight-loss in a short period or minimal weight-loss after six months. This was consistent with product or nationally agreed recommendations.

To access the weight-loss service, people needed to allow the pharmacy to contact their GP practice so that the prescriber could review their information that was relevant to prescriber's assessment. The weight management guidelines required the prescriber to share details of any prescribed treatment with the patient's GP. The superintendent added that this was usually done within one month of first prescribing a product.

The pharmacy team used baskets during the dispensing process to separate people's medicines and organise its workload. The pharmacy obtained its medicines from MHRA licensed pharmaceutical wholesalers and stored them in an organised manner. The team stored all temperature sensitive weight-loss products in medication refrigerators, which were temperature monitored. The pharmacy supplied a needles disposal bin, needles, and cleansing swabs with people's first weight-loss injection supply to help them safely self-administer their treatment.

The pharmacy had systems that showed it promptly and securely supplied temperature sensitive weight-loss products in good condition to people. The superintendent explained that the pharmacy usually prepared and packaged these products for delivery within fifteen minutes of them being removed from the refrigerator. The pharmacy team wrapped ice packs in waterproof bags to help keep weight-loss products cool and prevent them from being damaged during transit to people. The national courier contracted to deliver treatments to people collected packages from the pharmacy three times a day Monday to Friday, and delivered them Monday to Saturday, and on Sundays if this was pre-arranged. Recent data indicated that the courier delivered most packages within twenty-four hours of dispatch from the pharmacy. The icepacks and insulated packaging used in delivering weight-loss products showed that the cold chain was maintained in transit for forty-eight hours. The pharmacy team and courier communicated the expected delivery date and time to people. The courier took images at the destination address to confirm deliveries. The pharmacy monitored the courier's online delivery service tracking system to check the delivery status of outstanding packages in transit. The superintendent explained that a minimal number of dispatched deliveries were delayed in reaching or did not reach the patient.

The courier tried a second delivery to the destination address within twenty-four hours of the first delivery attempt. It held undelivered packages for ten days at its branch that was local to the patient for them to collect. The weight-loss products that required refrigeration had either a twenty-eight- or thirty-day stability outside of refrigerated conditions provided the product remained unopened. The courier returned the medication to the pharmacy for disposal if it remained uncollected, but this rarely happened.

The pharmacy disposed all weight-loss injections that the courier returned. The prescribers subsequently issued a new prescription for any medication that needed to be re-dispatched. This helped to maintain the prescribing and supply audit trail.

Most patients who initially reported to the pharmacy that they had not received their weight-loss product later found it when the courier's delivery records confirmed it had been delivered. Otherwise, the pharmacy asked the patient to obtain a crime reference number from the police.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment that it needs to provide its services effectively. And it has the facilities to secure people's information.

Inspector's evidence

The pharmacy team kept the dispensary sink clean, it had hot and cold running water, and a range of clean measures. So, it had the facilities to make sure it did not contaminate the medicines it handled and could accurately measure and give people their prescribed volume of medicine. Staff members had access to the BNF online, which meant they could refer to the latest pharmaceutical information if needed.

The pharmacy team had facilities that protected people's confidentiality. It viewed their electronic information on screens not visible to unauthorised persons and regularly backed up people's data on its PMR system. So, it secured people's electronic information and could retrieve their data if the PMR system failed. The staff spoke to people directly via the telephone. And members of the public did not visit the pharmacy, so it was unlikely that unauthorised persons could see patient data at the pharmacy.

The pharmacy' website stated that the pharmacy owner had established security standards and procedures to prevent unauthorised access to people's information by maintaining physical, electronic, and procedural safeguards that complied with applicable standards.

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.