General Pharmaceutical Council

# Registered pharmacy inspection report

**Pharmacy Name:** Milennium Pharmacy, 29-31 Shaw Street, St. Helens, Merseyside, WA10 1DG

**Pharmacy reference:** 9011768

**Type of pharmacy:** Community

**Date of inspection:** 17/04/2024

## Pharmacy context

This is a community pharmacy situated in the town centre of St Helens, in Merseyside. The pharmacy dispenses NHS prescriptions and offers NHS services such as a minor ailment service and emergency hormonal contraception. The pharmacy also dispenses private prescriptions, some of which are for aesthetic treatments and products sold through its website. And it has an on-site private clinic service provided by a pharmacist independent prescriber to treat some minor conditions. The pharmacy supplies medicines in multi-compartment compliance packs for some people to help them take their medicines at the right time.

## 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 | 1.2 | Standard not met | The pharmacy does not have written risk assessments for the aesthetic services it provides. So, it cannot show how it is managing risks effectively to provide its services safely. Members of the team do not consistently record things that go wrong so they can learn from them and may miss some opportunities to improve. |
| **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 not all met | 4.2 | Standard not met | Members of the team supply aesthetic treatments without having enough information to be able to provide assurance that they are being prescribed and administered appropriately. |
| **5. Equipment and facilities** | Standards met | N/A | N/A | N/A |

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

### Summary findings

The pharmacy has written procedures to help the team work effectively. But the procedures are not always followed. The pharmacy does not have written risk assessments for all the private services it provides. So, it cannot show how it is managing risks to provide its services safely. Team members do not always make records of dispensing mistakes, and this could make it harder for them to learn from them and to make the pharmacy's services safer.

### Inspector's evidence

The pharmacy provided some of its private services through its website https://www.millenniumaesthetics.co.uk/. A range of non-surgical cosmetic treatments were supplied to aesthetic practitioners 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. Aesthetic practitioners who wished to use the website were required to open an account which needed to be approved by a member of the pharmacy team.

For an account to be approved, an aesthetic practitioner had to provide a copy of their ID and evidence that they had completed a suitable course for the aesthetic product being requested. Products which they could select from the website depended on their qualification. And prescribers had to provide details of their professional registration, and evidence that they were competent to prescribe aesthetic products. But the pharmacy did not record the date that the checks were made when accounts were opened. Some occasional checks were completed on the registration of the prescriber when further prescriptions were supplied, however, there was no regular interval for these checks and there was no record kept. Which meant the pharmacy may not be aware if the registration status of a prescriber had changed and therefore were no longer entitled to prescribe. The SI provided an assurance that he would speak with the software developers to discuss ways in which links could be embedded to ensure checks could be carried out routinely. The pharmacy did not ask practitioners to provide proof of professional indemnity insurance. So, it could not provide an assurance that the people they treated would be appropriately protected. Practitioners were not able to place orders through the website until their 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. Or 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 pharmacy had written procedures for the aesthetics service to ensure team members fully understood their responsibilities and what was expected of them. But it did not have a written risk assessment to show how it had identified and managed the risks associated with the service and the treatments it supplied. The pharmacy team were able to give examples of steps that were taken to manage specific risks that were involved in providing the service at a distance. For example, there were quantity limits for the amount of botulinum toxin that could be supplied, aesthetic treatments and products were only delivered directly to the aesthetic practitioners, who then would be responsible for administering the product to the intended person. And the pharmacy had an account opening process.

The pharmacy also offered face-to-face consultations with a pharmacist independent prescriber (PIP). Treatments the PIP prescribed for included urinary tract infections (UTIs), fungal infection, weight loss,

acne, and oral contraception. There was a risk assessment for this service and clinical protocols. A template consultation form was included within the protocols which covered red flags, treatment plans and notification to the person's regular prescriber. However, the consultation form was not being used and the PIP was making notes on the person's electronic record. The superintendent pharmacist (SI) explained that the pharmacy supplied a very low volume of medicines via this route, and this was evident from the dispensing records seen. The PIP confirmed that people's regular prescriber was sent notification of treatment but evidence of this was not seen. There had been no audits or prescribing reviews undertaken since the start of the service to provide assurance that the prescribing was appropriate.

Standard operating procedures (SOPs) covering the services provided by the pharmacy team were available and had been read and signed by team members.

The pharmacy had a process to record dispensing errors and their learning outcomes. Near miss incidents were usually recorded on a paper log. The pharmacist discussed any learning points with team members at the point of identifying a mistake. However, no near misses had been recorded since 2023 and the near miss records were not reviewed regularly to help identify underlying factors. So, some learning opportunities could be missed.

The responsible pharmacist (RP) had their notice on display. The pharmacy had a complaints procedure, and a current certificate of professional indemnity insurance was on display.

Records for the RP, private prescriptions and emergency supplies appeared to be in order. Controlled drugs (CDs) registers were maintained with running balances recorded and checked at least monthly. Patient returned CDs were recorded in a separate register.

An information governance (IG) policy was available, and the pharmacy team had completed training on it. Confidential information was separated to be removed by a waste carrier.

Safeguarding procedures were in place. The pharmacist had completed level 2 safeguarding training. Contact details for the local safeguarding board were in the safeguarding folder. The delivery driver had read the SOPs for safeguarding.

## Principle 2 - Staffing ✔ Standards met

### Summary findings

There are enough staff to manage the pharmacy's workload and they are appropriately trained for the jobs they do. Members of the pharmacy team complete some additional training to help them keep their knowledge up to date.

### Inspector's evidence

The pharmacy team included a superintendent pharmacist, a pharmacist independent prescriber (PIP), two pharmacy technicians, six dispensers and two delivery drivers. Locum pharmacists also provided pharmacist cover. All members of the pharmacy team were appropriately trained or on accredited training programmes. The volume of work appeared to be managed. Staffing levels were maintained by team members and a staggered holiday system.

Members of the pharmacy team completed some additional training via the eLearning for health (elfh) portal. Training records were kept showing what training had been completed. The PIP provided private consultations on behalf of the pharmacy, and where he felt it was appropriate, would issue prescriptions. He had completed some training for the conditions which the pharmacy offered treatments for. But this was generally limited to reading national guidelines and other literature, and from his experience working at a GP practice. But he did not have any written records for the training he had completed. There was no additional training provided to locum pharmacists in relation to aesthetic products which were supplied from the pharmacy.

Team members gave examples of how they would sell a pharmacy only medicine using the WWHAM questioning technique, refuse sales of medicines they felt were inappropriate, and refer people to the pharmacist if needed. The pharmacist felt able to exercise his professional judgement, and this was respected by the SI and members of the pharmacy team. A dispenser said she felt a good level of support from the pharmacist and worked well with team members. Team members had annual appraisals with the SI. Members of the team were aware of the whistleblowing policy and said that they would be comfortable reporting any concerns to the SI. There were no targets set by the pharmacy for professional services.

## Principle 3 - Premises ✔ Standards met

### Summary findings

The pharmacy premises are clean and tidy and suitable for the services provided. A consultation room is available so people using the pharmacy can have a private conversation with its team members.

### Inspector's evidence

The pharmacy is located within a business unit which had been specifically refurbished for use as a pharmacy. It was clean and tidy, and appeared adequately maintained. The size of the dispensary was sufficient for the workload. People were not able to view any patient sensitive information. The temperature was controlled using air conditioning. Lighting was sufficient. There was a separate entrance with a screened counter for people who attended the pharmacy for substance misuse and needle exchange services.

Two consultation rooms were available, one of which was usually used as an office space. The space in the other room was clutter free with a computer, desk, seating, adequate lighting, and a wash basin. The entrance to the consultation room was clearly signposted and indicated if the room was engaged or available. The pharmacy had two websites, one for both NHS and private clinic services, and another for aesthetic treatments and products. Medicines were supplied directly to healthcare professionals via the aesthetics website. The website contained details of the pharmacy, but it did not show who the superintendent pharmacist was. . Following the inspection, this information was added and a screenshot was sent by the SI.

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

### Summary findings

The pharmacy does not always obtain enough information to help make sure that the aesthetic treatments it supplies are being prescribed and administered safely. The pharmacy gets its medicines from licensed suppliers and stores them properly. It responds appropriately to drug alerts and product recalls. This helps make sure that its medicines and devices are safe for people to use.

### Inspector's evidence

Access to the pharmacy was level and suitable for wheelchair users. There was also wheelchair access to the consultation room. Digital screens gave information about the services offered and information was also available on the pharmacy website.

The pharmacy had a delivery service for local NHS patients. An electronic device was used to keep a delivery record. Unsuccessful deliveries were returned to the pharmacy and a card posted through the letterbox indicating that the pharmacy had attempted a delivery. Signatures were obtained from the recipient when CDs were delivered, to confirm receipt.

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 people's prescriptions to avoid items being mixed up. The baskets were colour coded to help prioritise dispensing. The pharmacist performed a clinical check of all prescriptions and then signed the prescription form to indicate this had been completed. An accuracy checker was then able to perform the final accuracy check. Owing slips were used to provide an audit trail if the full quantity could not be immediately supplied.

The pharmacy used barcode technology to help manage some of its dispensary services, so that when a prescription was processed on the computer, and an audit trail showed it had been clinically and accuracy checked by a pharmacist. The required medicines were automatically ordered from the wholesaler and arrived in the same box. A member of the team then scanned the barcodes of the medicines, to print dispensing labels. The computer then instructed the team member to place the medicines into numbered baskets, which also had barcodes that were scanned to make sure the correct medicines had been placed into the correct basket. Each basket contained all the medicines for a specific person. Once the dispensing process had been completed for 20 people, the medicines were placed into bags for each person. An SOP was in place, and team members were suitably trained in the process.

The pharmacist was aware of the risks associated with the use of valproate during pregnancy. Educational material was provided when the medicines were supplied to people. The pharmacist had spoken to those who were at risk to make sure they were aware of the pregnancy prevention programme. And this was recorded on their patient medication record (PMR).

Some medicines were dispensed in multi-compartment compliance packs using an automated system. Before a person was started on a compliance pack the pharmacy referred them to their GP to complete a suitability assessment. A record sheet was kept for each patient, containing details about their current medication. Any medication changes were confirmed with the GP surgery before the record sheet was

amended. Hospital discharge information was sought, and previous records were retained for future reference. The compliance packs were labelled with medication descriptions, batch numbers and expiry dates. All compliance aids were accuracy checked after dispensing. But patient information leaflets (PILs) were not routinely supplied. So, people may not always have full up-to-date information about their medicines. From time to time the robot mis-dispensed compliance packs, and this was identified during the accuracy check. The compliance packs were corrected and the erroneous tablets removed. But no record was made of these errors and information was not shared with the manufacturers of the robot.

Electronic prescriptions were issued via the pharmacy's website for aesthetic treatments. These were authorised by UK prescribers. Prescriptions were signed by prescribers using a two-factor authorisation system where the prescriber was sent a PIN to their personal telephone or email. Once a prescription had been signed it could not be amended or changed by anyone including the prescriber. The pharmacy had a quantity restriction for medicines containing botulinum toxins, so that no more than five vials were permitted in any one order. Dispensed aesthetic products seen did not have patient specific directions on the label and had been labelled with 'as directed'. The pharmacy did not request any further detail about what treatment the medicine was being used for, and there was no evidence of intervention on any prescriptions containing multiple bottles. This meant the pharmacist may not always have enough information to clinically review whether a prescription was appropriate. It also meant this information could not be included on the medicine label to help ensure aesthetic practitioners use medicines in line with the prescriber's instruction.

The pharmacy's computer system displayed information relating to individual orders but did not show information about past orders unless this was independently searched for by a team member. This could mean that repeated requests were not identified. However, the SI gave an example of referring a prescriber to a regulatory body for inappropriate prescribing patterns that had been found. Current prescribing guidance for aesthetics treatments expects the prescriber to have a face-to-face consultation with the patient. Prescribers had to indicate that they had carried out a face-to-face consultation, but no further checks were carried out to help make sure this was taking place. Once the information had been processed on the computer, medicines were sent for delivery via courier or could be collected from the pharmacy counter. Medicines which needed to be kept refrigerated and were sent by courier were packaged in polystyrene with ice blocks. The pharmacy had sent out a test package with a temperature data logger to ensure medicines were stored at the required temperature during the delivery process.

People could visit the pharmacy for a face-to-face consultation with the PIP for treatments for a variety of conditions. The PIP used the pharmacy's PMR software to record consultation notes. A review of two records indicated consultations were conducted in line with accepted consultation models. A consultation record for a patient prescribed Ozempic for weight loss was seen. The percentage weight loss had been calculated at a follow up visit and a check for potential side-effects carried out. A review of the private prescription register did not indicate medicines were being overprescribed.

Medicines were obtained from licensed wholesalers, and any unlicensed medicines were sourced from a specials manufacturer. Stock was date checked each month. Short-dated stock was highlighted and recorded in a diary for it to be removed at the start of the month of expiry. Liquid medication had the date of opening written on. Controlled drugs were stored appropriately in the CD cabinet. 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 in the required range. Patient returned medication was disposed of in designated bins located away from the dispensary. 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.

## 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. And they maintain the equipment so that it is safe to use.

### Inspector's evidence

The pharmacy had calibrated glass measures and tablet counting equipment. Separate labelled measures were available and used for liquid CDs to avoid cross contamination. Equipment was clean and ready for use. A number of medical fridges were available. An automated device was used to measure liquid CDs when providing the substance misuse service. It was calibrated and cleaned daily. The robot used to dispense multi-compartment compliance packs had a service contract and was serviced annually. Members of the team routinely cleaned and maintained the robot. But they did not record this so could not show when cleaning and maintenance had been carried out.

Computers were password protected and screens were positioned so that they weren't visible from the public areas of the pharmacy. A cordless phone was available in the pharmacy which allowed team members to move to a private area if the phone call warranted privacy. Up-to- date reference sources were available.

## 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. |