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: 23/08/2023

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 medicines 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 aids 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	1.1	Standard not met	The pharmacy does not have written procedures for all of its services. And some of the procedures do not reflect current practice. So members of the team may not fully understand what their responsibilities are.
		1.2	Standard not met	The pharmacy does not have written risk assessments for the private services it provides. So it cannot show how it is managing risks to provide its services safely. Members of the team record things that go wrong so they can learn from them. But they do not review the records, so they 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	The pharmacy supplies medicines against electronic prescriptions which do not meet the requirements of an advanced electronic signature, and therefore are not valid. Members of the team supply aesthetic medicines without having enough information to be able to provide assurance that they are being prescribed and used appropriately.
		4.3	Standard not met	The pharmacy uses special packaging to protect cold chain aesthetic medicines during delivery. But it cannot demonstrate whether the packaging is effective. So it cannot provide assurance that the medicines will be in good condition when they are received.
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 do not always reflect current practice and do not cover all of the services provided. So members of the pharmacy team may not always fully understand what is expected of them. The pharmacy does not have written risk assessments for the private services it provides. So it cannot show how it is managing risks to provide its services safely. Members of the team record things that go wrong so they can learn from them. But they do not review the records, so they may miss some opportunities to improve.

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 did not have to be a healthcare professional. But they 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. 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. And it did not routinely check the registration of the prescriber when further prescriptions were supplied, which meant the pharmacy may not be aware if the registration status had changed and they were no longer entitled to prescribe. The pharmacy did not ask practitioners to provide proof of professional indemnity insurance. So it could not provide 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 did not have any written procedures for the aesthetics service to ensure team members fully understood their responsibilities and what was expected of them. And it did not have a written risk assessment to show how it had identified and managed the risks associated with the service and the medicines it supplied. The pharmacy team was able to give examples of steps that were taken to manage specific risks that were involved in providing this service at a distance. For example, there were quantity limits for the amount of botulinum toxin that could be supplied, aesthetic medicines 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) in its consultation room. Treatments the PIP prescribed included urinary tract infections (UTIs), fungal

infection, weight loss, acne, and oral contraception. The pharmacist had begun to write a procedure for the provision of the service, and this included how to record consultations and a prescription template. But the pharmacy had not completed a formal risk assessment for the service, and it did not have prescribing guidelines in place or a formulary for the conditions being treated. And the pharmacy had not reviewed the prescribing records, or completed an audit, to provide assurance that the prescribing was appropriate.

There was a set of standard operating procedures (SOPs) covering NHS services, which had been issued in December 2017, and reviewed in December 2019. But the procedures had not been updated or reviewed since then. And the pharmacy had more recently changed some of their processes, such as using a robot to dispense medicines in multi-compartment compliance aids. So this was not covered in the procedures which could cause misunderstanding. Some members of the pharmacy team had signed training sheets to show they had read and accepted the SOPs, but others had not. So the pharmacy could not demonstrate that all members of the team fully understood what was expected of them.

The pharmacy team kept records of dispensing errors and their learning outcomes. Near miss incidents were recorded on a paper log. The pharmacist discussed any learning points with team members at the point of identifying a mistake. But and the near miss records were not reviewed to help identify underlying factors. So some learning opportunities could be missed.

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 when they arrived all stock for this service was delivered in the same box. The 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 in 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. But the pharmacy did not monitor or review how well the automated system operated. And members of the team admitted there had been occasions where an insufficient quantity of medicines had been supplied. So the pharmacy may not identify weaknesses in the system or take action to address them.

Roles and responsibilities of the pharmacy team were described in individual SOPs. A trainee dispenser was able to explain what their responsibilities were and was clear about the tasks which could or could not be conducted during the absence of a pharmacist. Staff wore standard uniforms. The responsible pharmacist (RP) had their notice on display. The pharmacy had a complaints procedure. But there was no information about it on display, so people may not always know how to give feedback or raise concerns. 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. Two random balances were checked, and both were found to be accurate. Patient returned CDs were recorded in a separate register.

An information governance (IG) policy was available. The pharmacy team had completed IG training. When questioned, a dispenser was able to explain how 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. A dispenser said she would initially report any concerns to the pharmacist on duty. The pharmacy only supplied aesthetic products directly to aesthetic practitioners.

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), three pharmacy technicians, two of whom were trained to accuracy check, six dispensers, three of whom were in training, and a new starter. 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 part-time staff and a staggered holiday system.

Members of the pharmacy team completed some additional training, for example they had recently completed a training pack about infection control. Training records were kept showing what training had been completed. But further training was not provided in a structured or consistent manner. So learning needs may not always be fully addressed.

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 for which the pharmacy offered treatments. 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.

A trainee dispenser 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. But there was no formal appraisal programme to help identify team member's specific learning needs. 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. But the pharmacy's aesthetic website does not fully explain who provides the service, which could cause confusion.

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. Customers were not able to view any patient sensitive information. The temperature was controlled using air conditioning. Lighting was sufficient. Team members had access to a kitchenette and WC facilities. There was a separate entrance with a screened counter for people who attended the pharmacy for substance misuse and needle exchange services.

A consultation room was available. The space was clutter free with a computer, desk, seating, adequate lighting, and a wash basin. The patient 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 medicines 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 was, or details about the company ownership.

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

Summary findings

The pharmacy sometimes supplies medicines against electronic prescriptions that are not correctly signed and therefore not legally valid. And it does not always obtain enough information to be sure that the aesthetic medicines it supplies are being used safely. It gets its medicines from recognised sources, stores them appropriately and carries out regular checks to help make sure that they are in good condition. And it uses special packaging when it delivers medicines that need cold storage. But it hasn't tested the packaging, so it may not be effective.

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. Pharmacy staff were able to list and explain the services provided. The pharmacy opening hours were displayed.

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 patients' 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.

Dispensed medicines awaiting collection were kept on a shelf using a numerical retrieval system. Prescription forms were retained, and stickers were used to clearly identify when fridge or CD safe storage items needed to be added. Members of the team were seen to confirm the patient's name and address when medicines were handed out. But schedule 3 and 4 CDs were not routinely highlighted, so team members may not always remember to check the validity of the prescription at the time of supply. And high-risk medicines (such as warfarin, lithium and methotrexate) were not highlighted, so team members may not always be able to check they are being used safely. The pharmacist was aware of the risks associated with the use of valproate during pregnancy. Educational material was available to hand out when the medicines were supplied. The pharmacist had spoken to patients who were at risk to make sure they were aware of the pregnancy prevention programme. And this was recorded on their PMR.

Some medicines were dispensed in multi-compartment compliance aids using a robotic system. Before a person was started on a compliance aid the pharmacy would refer them to their GP to complete an assessment about their suitability. 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. Disposable equipment was used to provide the service, and the

compliance aids 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.

The pharmacy dispensed medicines for people who were residents of care homes. Each month, the pharmacy was provided with a re-order sheet which contained details about the medicines the residents required, any medication changes and handover notes for the pharmacy. When prescriptions were received from the GP surgery, they would be compared to the re-order sheet to confirm all medicines had been received back. Any queries were chased up with the GP surgery, and the care home was informed.

Electronic prescriptions could be issued via the pharmacy's website for aesthetic medicines. These were authorised by UK prescribers. The online system required prescribers to electronically draw their signature to authorise the prescription. And the process required members of the pharmacy team to compare the signature to that of a specimen. This does not meet the requirements of an advanced electronic signature. The pharmacy had a quantity restriction for medicines containing botulinum toxins, so that no more than 5 vials were permitted in any one order. But 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. Current prescribing guidance for aesthetics treatments expects the prescriber to have a face-to-face consultation with the patient. But some of the prescriptions for aesthetic treatments were authorised by prescribers who lived long distances away from where the medicines were being delivered. And the pharmacy team had not intervened to check whether a physical consultation had taken 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. But there were no records to show whether this method had been sufficiently tested to show it was suitable.

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. But the team could not find the record to show what had been date checked, which meant it was unclear when the last check had happened or whether all stock had been included. 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, with clear segregation between current stock, patient returns and out of date stock. 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

Team members had access to the internet for general information. This included access to the BNF, BNFc and Drug Tariff resources. All electrical equipment appeared to be in working order. There was a selection of liquid measures with British Standard and Crown marks. Separate measures were designated and used for methadone. The pharmacy also had counting triangles for counting loose tablets including a designated tablet triangle for cytotoxic medication. Equipment was kept clean. A Methameasure device was used to provide the substance misuse service. It was calibrated and cleaned daily.

The robot used to dispense multicompartment compliance aids had a service contract. There was an annual service by a technician. And 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. The consultation room was used appropriately. Patients were offered its use when requesting advice or when counselling was required.

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.