General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Manual Pharmacy, Unit 1, Verda Park, Hithercroft Road, Wallingford, OX10 9SJ

Pharmacy reference: 9012134

Type of pharmacy: Internet / distance selling

Date of inspection: 25/10/2024

Pharmacy context

This is a distance selling pharmacy located in a business park in Wallingford in Oxfordshire. The pharmacy dispenses lifestyle treatments including erectile dysfunction, hair loss, weight loss, and testosterone replacement therapy prescribed by healthcare professionals in its prescription service team.

Overall inspection outcome

✔ **Standards met**

Required Action: None

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 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 has assurances provided by the prescribing service on how they audit the quality of their clinical services. The pharmacy has access to people's consultation records so it can be clinically assured of how appropriate a prescribing decision is. The pharmacy's working practices are generally safe and effective. Although the RP doesn't carry out checks on every prescription, the pharmacy has other safeguards and tools in place to ensure that clinically safe prescribing is undertaken by the prescribers. And it monitors and assesses the safety and quality of its services through regular audits and clinical meetings. The pharmacy provides up-to-date clearly written procedures which tell team members how to work safely. It encourages people to give their views so it can improve its services. The pharmacy's team members mostly keep all the records they need to by law. They are trained in protecting the welfare of vulnerable people. And they keep people's private information safe.

Inspector's evidence

The pharmacy provided an online prescribing service for medicines used to manage a range of conditions. And these included weight management, hair loss, testosterone replacement therapy and erectile dysfunction. The pharmacy's prescribing service had been registered and regulated by the Care Quality Commission (CQC) since the previous inspection. Although the prescribing service was now under the regulation of the CQC, the pharmacy operations appeared to work as one. People who accessed the pharmacy's services were over 18 years old and living in the United Kingdom.

The pharmacy team members had a detailed onboarding process in place to assure themselves of the safety and quality of the prescribing service. They shared the risk assessments and clinical frameworks for the conditions that the prescribing service treated. The pharmacy team members were assured of how the prescribing service undertook photo identification checks. The pharmacy team had access to the prescribing services' clinical system. The service's prescribers assured themselves that the information entered by people using the service could not be changed to achieve a specific outcome. The superintendent pharmacist explained that the prescribing service team were exploring alternatives to strengthen how it verified the information people submitted. The pharmacy said it had robust safeguards and tools in place to ensure that clinically safe prescribing is undertaken by the prescribers.

Regarding weight loss management service and verification of medical history, GP notification was not mandatory. People were required to supply identification and body mass index (BMI) and the prescribing service could detect if photographic evidence had been modified. Around 20% of people were filtered out via the initial asynchronous questionnaire and following review by a clinician where they were deemed not suitable for treatment. The pharmacy had a policy from the prescribing service which ensured that prescribers issuing the prescriptions were appropriately registered, had the necessary scope of clinical knowledge to deliver the service and the correct indemnity cover should something go wrong. The pharmacy had direct access to the records and a system in place between the company's compliance and risk manager who monitored prescriber registrations.

The pharmacy had access to a person's consultation records so its team members would be able assure

themselves on the appropriateness of the prescribing decision. The pharmacy had assurances provided that the prescribing service were requesting consent from people using their service to share updated information on their treatment with their primary clinician (GP surgery). The pharmacy had assurances provided by the prescribing service on how they audited the quality of their clinical services, and this information was regularly shared with the pharmacy team in written submissions and team meetings.

Manual Pharmacy and the prescribing service had an agreement to conduct audits to make sure the prescribers were following processes such as requesting blood tests to check for markers before issuing a prescription. If the prescriber was found not to be following the process, then an action plan could be put in place. Prescribing audits were conducted at varying intervals subject to the treatment. So, there were three audits associated with weight loss and these were engagement, coaching and monitoring weight loss. There was a safety audit regarding prescribing and handling finasteride tablets. The pharmacy responded to audit findings and created an action plan if it identified shortcomings. The action plan was reviewed and discussed at monthly quality and weekly clinical meetings. The pharmacy tracked compliance of each audit scheduled for 2024 to ensure there were improvements in its processes.

The superintendent pharmacist (SI) could access the prescribing system and alert the pharmacy team regarding interventions. He could contact the customer care team via an internal communication system and tell them if an order was held and why. If needed, the SI could complete an incident report and log it on the electronic incident management system. It may be that the pharmacy required more information from the person who placed the order. The pharmacy reviewed clinical interventions in line with the incident report policy on a daily basis. The SI referred to a data dashboard to monitor prescription figures and check rate of prescribing.

The pharmacy had measures in place so it was a ‘safer workplace’ in all areas. The dispensary team had systems to review dispensing errors and near misses. Members of the team recorded near misses and discussed the mistakes they made to learn from them and to reduce the chances of them happening again. To help minimise picking errors, the team highlighted different strengths of the same medicines indicating a designated storage place for each strength. The dispensary team dispensed prescriptions at workbenches. The accuracy checking dispensers (ACDs) and the responsible pharmacist (RP) checked completed prescriptions before they were dispatched. The Responsible Pharmacist (RP) was responsible for clinically checking all prescriptions that were sent to the pharmacy to be prepared but at the time of the visit he was unable to demonstrate this was the case for every prescription. But the evidence seen, and subsequently provided, was mainly of operational rather than clinical interventions.

The pharmacy team logged incidents on the incident management system and these were then triaged, investigated, monitored in clinical meetings and closed once resolved. If someone reported a dispensing error, the pharmacy team completed an investigation to identify why the mistake happened and to help prevent the same mistake happening again. A patient safety review (PSR) was compiled of incidents such as dispensing incidents and discussed at the monthly quality meetings attended by representatives of all the teams.

The SI described regular clinical meetings attended by the medical officer, prescribers, clinical lead, customer care team representative and weight loss coach. The meeting was documented and the agenda included dispensing incidents, prescribing errors, clinical updates, SOPs, policies, onboarding, competency, frameworks and any other business for discussion.

The prescribing service had a robust auditing schedule which covered a number of different clinical and operational areas of focus. The timing of the audits ranged from monthly and quarterly to bi-annually. Where the outcomes of the audits did not meet the prescribing service's own 'standards met,' an action

plan was created and a re-audit took place. This information from the audits was shared with the pharmacy and discussed in the monthly team meetings. The pharmacy audits monitored operational processes such as the robots, fridge temperatures and security.

The prescribing service had registered with the Care Quality Commission (CQC) but they had not had an inspection at the time of this inspection. The prescribing team were located separately and remotely from the pharmacy.

People accessed a treatment or consultation via the website and completed a consultation questionnaire which was reviewed by a prescriber who evaluated the answers and information given by the person. There was an audit trail identifying the prescriber who could only use their own log-in and they had their own laptop and Google account. People who have had previous treatments could make a request to speak to the original prescriber. The prescriber checked the patient identification and age via an online identification system and for some services people had to provide photo identification, such as weight loss management and testosterone replacement therapy (TRT). The prescribing service had systems to detect multiple accounts and kept records of reasons to refuse supplies of medicines. The e-prescription was sent to the dispensary for dispensing. When a PIP issued a prescription, the person being treated also received a written Treatment Plan and a manufacturer's patient information leaflet (PIL). Pharmacist Independent Prescribers (PIPs) could be contacted and provide advice to patients via email, secure messaging or whatsapp."

The pharmacy had online standard operating procedures (SOPs) for most of the services it provided. And these were reviewed by the SI and the RP. The quality assurance process made sure members of the pharmacy team were required to read and understand the SOPs relevant to their roles and follow them. The pharmacy was able to explain the different roles people undertook at the prescribing service. The prescribing service had a chief medical officer, a GP clinical lead to oversee the entire service and a person responsible for risk and compliance. All PIPs were trained and could demonstrate competency across all the four clinical conditions, but they generally worked in condition-specific teams which were overseen by a specialist medical clinical lead for that treatment area. The specialist clinical leads for each area prescribed and oversaw the day-to-day running of the service as well as undertaking area specific audits and reviewing relevant procedures and policies.

The pharmacy's complaints policy signposted people to The Centre for Effective Dispute Resolution (CEDR) whose role was to help customers and businesses to resolve disputes if they were unable to resolve their complaints directly through the organisation's own complaints procedure. People could leave feedback via an email address in "Terms and Conditions." And via Trustpilot. People could use the website chat function.

The pharmacy kept a record to show who was the RP and when. And displayed a notice that told people who the RP was. The pharmacy team recorded the private prescriptions dispensed daily and collated the records to create a private prescription register which was retained digitally on the database. Members of the pharmacy team recorded Interventions on a secure messaging tool and contacted the prescriber if necessary. The SI could see clinical records and retained digitally on the database and a view of letters regarding treatment to the person's usual prescriber. The pharmacy retained certificates of conformity for the unlicensed (specials) medicines it obtained for supply on prescription. These were usually preparations. It did not obtain or supply any controlled drugs (CDs) which had to be recorded in a CD register. Interventions were recorded in line with Incident Management policy and were also noted on the patient medication record (PMR) if needed. The pharmacy had access to the prescribing service's consultation system where all records of interaction between the prescriber and the person using the service was documented. The pharmacy also kept a prescription register required by law and a record of the supply of the medicines on its own dispensing system.

The pharmacy was registered with the information commissioner's office (ICO) and displayed the privacy policy on the website telling people how their personal information was gathered, used and shared by the pharmacy and its team. The SI explained that the pharmacy computer system had different levels of access as needed by team members. The pharmacy team members disposed of confidential wastepaper securely.

The customer service and prescribing service teams were required to undertake a set of mandatory training which included safeguarding training. The safeguarding lead was trained to level 3 and other members of the teams were trained to level 1 or 2. The pharmacy required people accessing its services to produce photo identity verification along with a credit check. The team described one recent example of a safeguarding incident which they referred onto appropriate authorities.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy's team members work well together to deliver its services safely and to manage the workload. They are well trained and supported in keeping their knowledge and skills up to date. They work effectively within their level of competence. Pharmacy team members can provide feedback and raise concerns about the pharmacy.

Inspector's evidence

On the day of the visit, the SI was supported by the RP, and nine full-time dispensers which included five accuracy checking dispensers who were in training or qualified. Trained pharmacy support staff had assisted with de-blistering tablets and putting away stock. The pharmacy's prescribing service consisted of eight PIPs who did not work at the pharmacy. The pharmacy employed dietician and nutritionist support and three medical professionals to deliver the weight loss service. They did not work at the registered pharmacy premises. The customer care team provided the principal initial contact for members of the public contacting the pharmacy.

The members of the different teams were required to read the standard operating procedures (SOPs) appropriate to their roles. The induction process for new team members was documented and included competencies, specific training for job roles and mandatory training in line with safer workplace. Team members completed training specific to their job role. The RP was required to complete an onboarding process which included mandatory training. However, this did not include clinical training in the conditions for which it provided its dispensing services. Mandatory training was completed online via a portal and monitored by line managers. Topics included: Safeguarding, Information governance and GDPR, Equality, Diversity and Human Rights, Fire safety, Health, Safety and Welfare, Anti-bribery and Corruption.

Team members had protected learning time to complete ongoing training. They had regular one-to-one appraisals with their line managers to identify areas for development. And they attended frequent internal team meetings to discuss changes in workflow. Pharmacy team members felt able to make suggestions and provide feedback and had suggested changing how people's goods were dispatched in more appealing packaging.

The pharmacy could demonstrate that the prescribing service and its prescribers have the necessary knowledge and skills to deliver the services and they keep up with these skills and any new developments. The pharmacy demonstrated an understanding of the onboarding process where each PIP must familiarise themselves with the clinical frameworks for the conditions it provides a service for. Ongoing training and supervision were provided by the medical clinical leads for each clinical condition. The RP was required to complete an onboarding process which included mandatory training and competencies specific to the role as RP. However, it was noted that this did not include any additional clinical training specific to the pharmacy's services. The prescribers did not have any targets or incentive schemes.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy generally keeps its websites up to date with the pharmacy's name, owner, address, SI and registration details. And it displays current information about its prescribers and online prescribing services. The pharmacy's premises are clean, secure and suitable for the provision of its services. The pharmacy prevents people accessing its premises when it is closed so that it keeps its medicines and people's information safe.

Inspector's evidence

The pharmacy had two websites at the time of the inspection visit. Manual.co offered treatment for a number of conditions including weight management, hair loss, testosterone replacement therapy and erectile dysfunction. JoinVoy.com was wholly dedicated to weight loss services. The websites for the prescribing service presented questionnaire-based assessments and consultations and support for most of its services. The websites informed people who their medical and pharmacist prescribers were. The websites encouraged the use of discounts on the initial order for treatment which have been referred to the MHRA for guidance. Some of the pharmacy address details on the website required updating to match the GPhC register.

The pharmacy's premises were in a unit in a business park on the outskirts of Wallingford in Oxfordshire. The access to the premises was secure, the pharmacy was clean and well-lit with natural light and air-conditioning controlled the environment. The pharmacy, its facilities and equipment were cleaned regularly.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy's services are easily accessed via their websites, telephone or email. The pharmacy has suitable assurances regarding the prescribing service, its prescribing policies and how it manages and identifies risk. It can show how people's information is verified and how people with certain conditions are followed up. The pharmacy obtains its medicines from reputable sources and stores its medicines stock securely at the right temperature. It makes sure people have the necessary information such as patient information leaflets and treatment plans that will help them to use their medicines safely. The pharmacy team members know what to do if any stock needs to be returned to the suppliers.

Inspector's evidence

The pharmacy's prescribing service was accessed via the websites. People could telephone or email the pharmacy if they wanted advice. And people could contact their assigned coach via the Voy App. The number of people providing consent to share information with their primary clinician (usually their GP) was low but the pharmacy was able to demonstrate examples of where the prescribing service shared information of a person's treatment with their primary clinician when consent was provided.

The pharmacy had the necessary due diligence and on-boarding processes in place to be assured of the safety and quality of the prescribing service for which it was providing a dispensing service. The pharmacy could be assured of the individual prescribers, the clinical prescribing policies and how risks were identified and mitigated. It requested indemnity arrangements and registration details for all the prescribers which were documented and monitored. The pharmacy provided information on how the identity of patients was verified and it was able to confirm if treatment details were shared with a person's primary carer. The pharmacy could provide information on how the quality of its services was monitored and how people were followed up as required for the conditions. The pharmacy team members were able to demonstrate evidence of the prescribers making necessary interventions at the required times in line with the clinical frameworks for each condition. These interventions were recorded in people's medical records as well as an internal patient safety monitoring platform. Information on the number of requests rejected was shared with the pharmacy.

The prescriber could see all the information in a person's consultation record each time they were accessing it to prescribe. And they could see if the person had changed any answers. The prescriber was able to free-type a message to the person via their account if there were concerns. Some private services had longer appointments. The prescriber recorded video conference calls such as for TRT on a specific account which the pharmacy team accessed when needed. The TRT lead was a doctor. The pharmacy supplied people with patient information leaflets (PILs). And they provided counselling through the PMR or their treatment plan.

The prescribing service requested photographic evidence for those using their weight loss service to verify the body mass index (BMI) that the person had recorded. The pharmacy used an artificial intelligence tool to ensure that the images had not been altered. The SI explained that they were exploring alternatives to strengthen how it verified the information people submitted.

The prescribing service had a robust auditing schedule which covered a number of different clinical and

operational areas of focus. The information from the audits and action plans was shared with the pharmacy and discussed in the monthly team meetings. The SI explained that the RP had access to the prescribing services clinical system and could view each prescription. Although during the visit, the RP did not undertake a clinical check on each prescription. Furthermore, the RP had not taken any additional training in the clinical areas the pharmacy offered which could contribute to clinical checks. The pharmacy team was sent the outcomes of the regular audits the prescribing service would undertake and was involved in monthly quality reviews at the multi-disciplinary team meetings.

The pharmacy removed tablets such as finasteride 1mg from their original manufacturer's packaging and repacked them in the pharmacy's own packaging which was sustainable. And the packaging had a barcode which could be scanned to see the drug name and expiry date. During the visit, the de-blistering process had finished. The SI explained that people could scan the barcode to access this information. This information was also available on the dispensing label, within the patient's treatment and on the patient's account."

The SI explained that members of the warehouse team operating the automated equipment cleaned it out between each type of tablet. They recorded the batch number and expiry date for tablets as part of the process to create an audit trail so individual batches could be traced in the event of a recall.

The pharmacy had risk assessments and audits to monitor aspects of the services such as consent, cold chain deliveries and packaging, and failed deliveries (how many were returned to the pharmacy). The pharmacy used tracked 24- and 48-hour courier delivery service. The pharmacy's customer base was in the United Kingdom (UK). And the RP was present when the courier collected packages for dispatch. Members of the team packed the items into strong, plain cardboard boxes which protected the contents and the recipient's privacy.

Medicines requiring refrigeration during transportation and storage were packed in insulated packaging and delivered with ice packs. The wool based packaging had been audited using a data logger over 24 hours at different times of year. If a delivery containing a medicine requiring refrigeration had failed, a new supply was issued for re-delivery to minimise the risk of medicines being supplied which were not maintained within the manufacturer's recommended temperature range. The pharmacy business continuity plan was reviewed regularly and described measures such as emergency lighting, a back-up generator and staffing to ensure people's medicines were supplied as normal.

The pharmacy used recognised wholesalers to obtain its pharmaceutical stock. It kept most of its medicines and medical devices in their original manufacturer's packaging. The pharmacy team checked the expiry dates of medicines. The pharmacy stored its stock, which needed to be refrigerated, between two and eight degrees Celsius. The pharmacy had procedures for handling obsolete medicines. And these medicines were kept separate from stock in pharmaceutical waste bins. The pharmacy had a procedure for dealing with alerts and recalls about medicines and medical devices. And the RP described the actions they took and what records they kept when the pharmacy received a concern about a product.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the facilities and equipment it needs for the services provided. The pharmacy uses its equipment appropriately to keep people's private information safe.

Inspector's evidence

The pharmacy team had access to a range of online reference sources such as the electronic BNF. The pharmacy had several refrigerators to store pharmaceutical stock requiring refrigeration and freezers for frozen ice packs. And its team regularly checked the maximum and minimum temperatures of each refrigerator, and they were serviced every six months.

The pharmacy's equipment was portable appliance tested (PAT). The pharmacy used robots to de-blister and repackage tablets. A member of the team explained the process which had been risk-assessed and there was an SOP. The robots were serviced regularly and cleaned between de-blistering different drugs. The team member explained that the pharmacy maintained records of what medicines were processed and their batch numbers and expiry dates to be able to trace medicines in the event of a recall.

The team could dispose of confidential waste appropriately. The pharmacy restricted access to its computers and patient medication record system. And only authorised team members could use them when they put in their own password. The pharmacy positioned its computer screens so they could only be seen by members of the pharmacy team.

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.