General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Online Pharmacy 4U, Unit 2, Mansfield Woodhouse Station Gateway, Signal Way off Debdale Lane, Mansfield Woodhouse, Mansfield, Nottinghamshire, NG19 9QH

Pharmacy reference: 9011972

Type of pharmacy: Internet / distance selling

Date of inspection: 12/02/2024

Pharmacy context

This distance selling pharmacy is in a small business centre in Mansfield Woodhouse, Nottinghamshire. It provides private prescribing and dispensing services to people through its website online-pharmacy4u.co.uk. It sells a range of healthcare products and medicines through its website. People can nominate the pharmacy to receive and dispense their NHS prescriptions. And it dispenses some medicines in multi-compartment compliance packs, designed to help people to take their medicines through its NHS service. The pharmacy premises are not accessible to members of the public.

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	Pharmacy team members do not work in accordance with the pharmacy's risk assessments and policies when prescribing and supplying prescription-only medicines and when selling over-the-counter P medicines through the online services provided. And the pharmacy does not use relevant information such as national prescribing safety updates to inform the contents of its risk assessments.
		1.2	Standard not met	The pharmacy does not undertake audits to support it in monitoring the safety and quality of the services it provides and to help it identify areas for learning and improvement.
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 does not have adequate safeguards in place to make sure it always confirms people’s diagnosis and suitably verifies information before prescribing medicines for long-term conditions and for medicines requiring ongoing monitoring. It does not have a robust process to share what it prescribes with people's regular prescribers. And it does not always make the necessary checks when supplying people with over-the-counter P medicines.
		4.3	Standard not met	The pharmacy does not have adequate processes for managing its waste medicines and any patient returned medicines it may receive.
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance Standards not all met

Summary findings

The pharmacy does not identify and manage all risks for the services it provides. It does not follow its own policies and risk assessments when supplying medicines online. And it does not engage in ongoing audit processes to support it in monitoring risk and identifying areas for continual improvement. The pharmacy uses technology to support it in identifying mistakes made during the dispensing process. But it does not record these mistakes to help share learning. The pharmacy clearly advertises how people can provide feedback about its services and it regularly responds to the feedback it receives. It keeps the records it needs to by law up to date and it protects people's confidential information appropriately.

Inspector's evidence

The pharmacy provided all its services at a distance through its website. It had current standard operating procedures (SOPs) relevant to its services and to support its team members using its patient medication record (PMR) system. But not all team members had signed the SOPs to confirm they had read and understood them. Team members showed insight into their individual roles and felt confident in referring queries to the superintendent pharmacist (SI), who worked at the pharmacy full-time as the responsible pharmacist (RP). The pharmacy also employed a nurse independent prescriber (NIP) who worked as its sole prescriber.

The pharmacy had risk assessments for the services it provided, including the conditions it prescribed for. It had a separate risk assessment for prescribing and supplying higher-risk medicines. This risk assessment included medicines used to treat long-term conditions, testosterone replacement therapy and antibiotics. Risk assessments included inclusion and exclusion criteria and age restrictions. They also set out a need to seek permission to check people's NHS Summary Care Record (SCR), if they had one, and a need to verify medical conditions before prescribing medicines for long-term conditions. The risk assessments provided information about when to refer a person to a GP. And they included quantity limits, to ensure people were not over-ordering over a defined period. The team routinely checked people's order history when prescribing and supplying medicines. And communication records between the pharmacy and NIP provided examples of requests being declined due to insufficient timeframes between requests. But there was an example of a person receiving two different medicines used for weight loss within a four-day period. The NIP explained they would not interchange medicines used for weight loss normally and this had been an error.

Risk assessments were not always updated in response to new information such as national patient safety alerts. For example, the risk assessment for the weight loss service did not consider national prescribing instructions issued by the Department of Health and Social Care in August 2023 and a further update to these instructions issued in January 2024 restricting the use of some medicines commonly used to support weight loss but licensed for the treatment of diabetes. Both the SI and NIP stated they were not aware of this update. And as such not all medicines for weight loss had been prescribed following the instructions. The risk assessment for the weight loss service did not require the NIP to independently verify a person's weight beyond the information provided within the consultation questionnaire to ensure the treatment was clinically appropriate to prescribe. A sample of prescribing records checked during the inspection found risk assessments were not always being followed. For

example, there were examples of people receiving treatment for long-term conditions without independent verification of them having the condition. And without providing evidence of recent monitoring checks, such as blood tests. Baseline bloods for people commencing on testosterone replacement therapy for male hypogonadism were not completed. Following the inspection, the NIP provided a reflective summary of learnings from the findings shared with them.

A risk assessment set out the need for increased monitoring checks when selling Pharmacy (P) medicines known to be subject to abuse. And team members had engaged in some learning to support them in identifying these medicines. One P medicine subject to abuse was managed through the pharmacy's prescribing service which required an online consultation prior to a prescription being issued. Records of these consultations included clear rationale for prescribing. But other records for the sale of P medicines identified that a pharmacist did not always review information within P medicine questionnaires to ensure the medicine was suitable for a person. For example, a record showing two codeine-based pain killers within the same transaction had been processed and the medicine dispatched. The SI explained this one had slipped through the net. Further records of P medicine sales showed not all P medicines were accompanied by an appropriate questionnaire. The company director, who worked within a customer service role in the pharmacy, provided information about problems with the pharmacy's website causing this issue. And the pharmacy had appointed developers to build a new website. But the pharmacy did not act to suspend broken listings whilst fixes were applied to its current website, or until its new website was operational. This meant people could request to purchase some P medicines without being prompted to complete a questionnaire. The SI explained he would contact people for further information to ensure the sale of a P medicine was appropriate and discussed an example of this. But they did not document these conversations to support their own decision making and people's continual care needs.

The pharmacy had not completed any clinical audits or prescribing reviews since launching its services. So, there were missed opportunities to identify situations where the team was not following the pharmacy's own policies. The SI demonstrated data that had been pulled from the pharmacy's computer system in preparation for an audit on the supply of P medicines. But this audit had yet to be carried out. The pharmacy did routinely check people's order history as part of its manual checking processes. These manual checks also looked for people attempting to create multiple accounts to purchase medicines. The pharmacy had a safeguarding procedure. And its team members engaged in safeguarding learning as part of their GPhC accredited training courses. The SI and NIP had completed safeguarding training to support them in their roles.

The pharmacy team used the functions of its PMR system to support a series of checks throughout the dispensing process. This relied on barcode technology to complete checks during the assembly process and the final accuracy check of the medicine. The PMR flagged any prescriptions requiring a clinical check to the attention of the pharmacist. The SI discussed how the PMR identified mistakes made during the dispensing process, known as near misses. And the PMR did not produce dispensing labels until a near miss was rectified. But the team did not take the opportunity to record these mistakes. The SI could not recall a mistake involving a medicine which could not be scanned through the PMR system. And they demonstrated how the system was updated regularly to include the barcodes of medicines that would not previously scan to reduce the number of manual checks during the dispensing process. The pharmacy had an incident reporting process for managing mistakes found following the supply of a medicine to a person, known as a dispensing error. The SI stated there had been no errors reported to them to date. The pharmacy had a complaints process, and this was clearly advertised on its website. It informed people how to escalate a concern to the GPhC if they were unhappy with the pharmacy's response. But it did not provide details of how a person could follow NHS complaints procedures if their concern was about a specific NHS service. The pharmacy regularly responded to feedback left through a

third-party review provider.

The pharmacy had current indemnity insurance arrangements for its services. And it had informed insurers of the prescribing services it provided. The SI stated the NIP also had their own indemnity insurance arrangements. But evidence of this was not retained by the pharmacy. The RP notice provided the correct details of the RP, and this notice was also available on the pharmacy's website. A sample of legally required records were seen to be kept in good order. The pharmacy kept running balances in its controlled drug (CD) register and it completed regular balance checks of stock medicines against the balances recorded in the register. The pharmacy held people's confidential information securely on password protected computers. And mostly within the registered premises. Prescribing records held by the NIP were on an encrypted laptop used for work purposes only. The pharmacy disposed of confidential waste securely.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy employs a small team of suitably skilled people to carry out its services. Pharmacy team members engage in learning relevant to their roles. They feel supported and able to feedback at work, and they know how to raise a concern.

Inspector's evidence

The SI and the company director held full time roles in the pharmacy. The director completed tasks associated with customer service. This included responding to feedback and queries from people using the pharmacies services, they did not complete dispensing tasks. The NIP worked remotely, a trainee dispenser, a delivery driver and a qualified dispenser also worked at the pharmacy. The trainee dispenser worked in a picking and dispatch role. And the qualified dispenser worked to support the delivery of NHS services. Another team member completed some cleaning and packaging replenishment tasks in the pharmacy on an ad-hoc basis. The pharmacy had business continuity arrangements if the prescriber was unavailable. This involved turning off the prescribing service function on the pharmacy's website.

The trainee dispenser was enrolled on a GPhC accredited training courses to support them in their role. The dispenser was enrolled on a pharmacy technician training programme, and they provided examples of how the SI worked to support them in this role. The pharmacy had obtained evidence of some ongoing learning the NIP had completed to support them in their role such as for menopause, women's health, and respiratory health updates. The SI was nearing the end of training to become an independent prescriber.

The pharmacy did not set targets or incentives for any of its services. The NIP had the autonomy to decide if they issued a prescription and stated if they were unsure, they would not prescribe. For example, they had referred a person requesting cyclizine to their own GP after a review of the information available to them. The NIP and pharmacy communicated through a secure web-based platform and examples of messages included queries and rejected orders were seen. The NIP described how they had sight of people's order histories to help inform prescribing decisions and considerations about ongoing monitoring requirements. They documented the discussions they had with people about ongoing monitoring and safety netting advice within the consultation summary notes. These notes were attached to prescriptions and available to the pharmacy team. The pharmacy had a whistleblowing policy and its team members understood how to raise concerns at work. Pharmacy team members communicated through continual conversations and felt able to feedback their ideas and thoughts at work.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy is adequately maintained, safe and secure. The pharmacy’s website provides relevant information to people to support them in accessing the pharmacy’s services.

Inspector's evidence

The pharmacy premises were secure from unauthorised access. They were clean and maintained appropriately. Air conditioning helped to maintain an ambient temperature and lighting was bright. Team members had access to handwashing facilities. The premises consisted of one large room used as the dispensary with staff facilities located in a small room off the dispensary. The dispensary had extensive shelving used to store toiletries, healthcare items, medicines, and medical devices. This limited the amount of available workspace for dispensing and packing activities. Team members demonstrated how they used the available space to manage workflow safely.

People accessed the pharmacy’s private services through its website. The website required people to start a consultation from a conditions page as required by GPhC guidance. People accessing the pharmacy’s prescribing services could read more information about specific treatments. A ‘start consultation’ button on treatment pages returned people back to the conditions page to start their consultation. The wording of this button potentially risked confusing people about the need to start their consultation from the conditions page. The website displayed other relevant information about the pharmacy and provided a link for people to check the pharmacy’s details on the GPhC register. But the pharmacy did not always keep information on its website up to date. For example, the website provided details of a pharmacist independent prescriber (PIP) that no longer worked at the pharmacy. And the pharmacy had not updated information about the third-party provider it used when checking people’s identities. The website provided details of the SI and of the NIP. But a link through to the Nursing and Midwifery Council (NMC) register and GPhC register did not work. This made it more difficult for people wishing to check the registration status of the healthcare professionals the pharmacy employed.

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

Summary findings

The pharmacy does not manage all its services safely, including its private prescribing services. It does not always obtain the information it needs before prescribing medicines for some health conditions and treatments. It does not have a satisfactory process to share information with people's regular prescribers. And its systems do not have the necessary safeguards to make sure people receive over-the-counter medicines that are suitable for them to take. The pharmacy does not have adequate arrangements to dispose of medicine waste. It obtains its medicines from reputable sources, and it responds to concerns it receives about medicines appropriately to ensure they remain safe and fit to supply.

Inspector's evidence

People accessed the pharmacy's services through its website. They could also nominate the pharmacy to dispense their NHS prescription. And they could telephone or email the pharmacy team for support and speak to the prescriber directly. The private prescribing service required people to complete a consultation questionnaire. People were asked to complete a questionnaire for most P medicines. But some P medicine questionnaires did not generate correctly which meant not all questions were available for people to answer. And in some circumstances a questionnaire did not generate at all. This meant there was a reliance on the pharmacy team identifying P medicines in order to ensure appropriate information was asked before a supply was made. A sample of completed questionnaires found medicines had been supplied without appropriate supporting information being obtained. For example, a supply of chloramphenicol eye ointment had been supplied for a condition which was not within its product licence. And benzyl peroxide gel had been supplied despite a person answering no to a safety statement asking them to confirm they would read the patient information leaflet, and that they accepted the pharmacy's terms and conditions.

The pharmacy advertised its identity checking procedure to people accessing its prescribing service. But it had not updated this to include the details of the third-party identity checking provider it used. People accessing the prescribing services were also asked to consent to their SCR being accessed and for information to be shared with their regular prescriber. The majority of prescribing was for testosterone replacement therapy for males, weight loss medicines and a range of long-term conditions. There was evidence of prescription requests being rejected and the majority of prescriptions seen were for single transactions. The prescriptions were written by the NIP and clinically checked by the SI.

For the prescribing service, people completed an online questionnaire which covered key areas such as medical history and any risk factors that could exclude the person from accessing treatment. The NIP reviewed completed questionnaires issued an electronic private prescription if a supply was deemed appropriate. The NIP explained how they would correspond with a person by telephone or email after they submitted the questionnaire. And discussed how they would seek further information from a person in the event the SCR did not have the information required, or a SCR was not available. The NIP then documented the consultation on their own internal record and put a summary of the consultation on the private prescription for the pharmacy team to see. And the pharmacy team was able to communicate with the NIP directly through a secure messaging channel in the event of queries about a

prescription. Records examined found the NIP did not always independently verify a person's medical condition or acquire evidence of ongoing monitoring where required before issuing a prescription. For example, the pharmacy had dispensed a prescription for metformin and ramipril, used to treat long-term diseases. But there were no documented blood tests nor did the SCR show this person had received this medicine before. In some instances, people provided information from other private healthcare providers, including healthcare providers located outside of the UK. There were no assurances provided about how the NIP or pharmacy team verified the legitimacy of these records.

The pharmacy asked people to consent for information about the treatment provided by the pharmacy to be shared with their regular prescriber and they were asked to provide details of their own GP. The director stated the service provided people with a template letter about the treatment prescribed, and they were encouraged to share this with their regular prescriber. The director also demonstrated a template letter that would be sent to people's regular prescribers by post following a treatment being prescribed, as required in its own policies. But the pharmacy did not retain evidence of any correspondence it shared with people's regular prescribers. And there was no evidence of correspondence received back from GP surgeries in response to any notifications sent by the pharmacy. This meant the pharmacy did not always have assurance that their regular prescriber was aware of any treatments prescribed through its services, especially medicines requiring ongoing monitoring such as those used for weight loss and long-term conditions.

The pharmacy team used functions on the PMR to support it in supplying medicines in multi-compartment compliance packs for NHS prescriptions. This included recording details of changes to people's medicine regimens. The pharmacy supplied patient information leaflets (PILs) when supplying medicines in original containers, but it did not always supply PILs when supplying medicines in compliance packs. It used audit trails to support the entire dispensing process, including the delivery of medicines to people's homes. These were either delivered by the delivery driver or sent via a tracked delivery service. It used packaging specifically designed to maintain the cold chain when supplying medicines requiring refrigeration to people. And the director discussed the checks they had made with the packaging manufacturer to assure themselves the pharmacy was using suitable packaging for these medicines and delivery times were met. The pharmacy had some information to support ongoing monitoring checks associated with the NHS prescriptions it dispensed. This included information about the checks for supplying medicines to people on pregnancy prevention programmes (PPPs). The SI knew about recent legal changes to the supply of valproate in original packaging. And understood the checks associated with the valproate PPP and explained the pharmacy had not dispensed to a person in the at-risk group to date.

The pharmacy obtained its medicines from licensed wholesalers. It stored them in an orderly manner on shelves throughout the dispensary. It held medicines requiring cold storage in a medical fridge. And it monitored and kept a record of the operational temperature range of the fridge to assure itself the medicines inside were held at the right temperature. The pharmacy held its CDs securely in a cabinet. Pharmacy team members checked expiry dates of medicines during the dispensing and supply process. But the pharmacy did not carry out scheduled date checks across all of its stock. No out-of-date medicines were found during a random check of dispensary stock. The pharmacy did not have medicine waste bins available for the safe disposal of any returned medicines or out-of-date medicines. The SI stated they had tried to set up arrangements but couldn't and as such had continued to take medicine waste to another pharmacy for safe disposal when this was needed. A discussion reiterated the need for the pharmacy to have its own system to manage waste medicines itself. The pharmacy received alerts about medicines that may not be fit for purpose by email. And it kept an audit trail of the action it took in response to these alerts.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has appropriate equipment available to provide its services. And its team members use the equipment in a way which protects people's confidentiality.

Inspector's evidence

Pharmacy team members had access to electronic reference resources via the internet and PMR system. Equipment to support the provision of services was readily available. For example, equipment to support the safe packaging of liquid medicines and the supply of medicines in multi-compartment compliance packs. Electrical equipment was in good working order and was visibly free from wear and tear. Pharmacy team members used NHS smart cards and passwords to access people's records. Access to the premises was restricted and as such people's personal information was protected from unauthorised access.

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.