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: 17/07/2023

Pharmacy context

This distance selling pharmacy is within 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. And people can nominate the pharmacy to receive and dispense their NHS prescriptions. 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	The pharmacy's risk assessments do not include all the services associated with the medicines it supplies through its website. And its team members do not always follow the procedures and policies designed to manage risk.
		1.2	Standard not met	The pharmacy does not monitor the safety and quality of its prescribing service. It does not undertake audits associated with this service. And it does not make checks to ensure its system-led processes are working in practice.
		1.8	Standard not met	The pharmacy does not have appropriate safeguards to prevent it in making repeat supplies of medicines subject to abuse, misuse and overuse.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	The pharmacy's website allows people to start a consultation from the page of an individual prescription-only medicine (POM). And wording on some pages associated with POMs promotes a transactional element not in keeping with a professional prescribing service.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not always show how it verifies medical information before issuing a prescription. And it does not follow its own processes by informing people's usual prescriber of the medicines it supplies, particularly when ongoing monitoring is required. Information within the pharmacy's consultation questionnaires is not always relevant to the medical condition people are seeking treatment for.
		4.3	Standard not met	The pharmacy does not store all its medicines securely as required by law. And its processes do not prevent access to these medicines when a pharmacist is not present. The pharmacy does not have adequate processes in place to manage its

Principle	Principle finding	Exception standard reference	Notable practice	Why
				waste medicines and patient returned medicines.
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 the risks associated with its services. It does not complete risk assessments for all its services associated with supplying medicines online. And it does not engage in ongoing audit processes to support it in monitoring risk. The pharmacy does not demonstrate appropriate safeguards to prevent repeated supplies of medicines subject to abuse, misuse, and overuse. And it supplies some medicines without independently verifying relevant clinical information. The pharmacy has some processes designed to share learning following mistakes. But it does not regularly record mistakes made during the dispensing process. This means there may be some missed opportunities to share learning and to reduce risk. The pharmacy clearly advertises how people can provide feedback about its services. It generally 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 employed a nurse independent prescriber (NIP) who prescribed medicines for a range of conditions. It had experienced a significant increase in the volume of NHS prescriptions it dispensed in May 2023 with a ten-fold increase in prescriptions received through this service. The pharmacy had current standard operating procedures (SOPs) relevant to most of its services. These were in the form of templates created by a pharmacy consultancy company. But the pharmacy had not personalised the SOPs for its own use. And specific procedures related to the online sales of medicines were not available. The pharmacy held the SOPs electronically and team members could access them. But there were no training records associated with the SOPs.

The pharmacy had prescribing risk assessments that covered a range of conditions including asthma, hypothyroidism, hypertension, skin conditions, hair loss, period delay, cystitis, migraine, and emergency hormonal contraception (EHC). A risk assessment for weight loss only included one treatment, it did not consider risks associated with injectable weight loss treatments and off-label prescribing supplied by the pharmacy. And a risk assessment had not been completed prior to prescribing and supplying testosterone gel. Written risk assessments were not available to support all conditions listed on the pharmacy's website. For example, hormone replacement therapy, and the sale of Pharmacy (P) medicines. The pharmacy's NIP was able to demonstrate verbally what they would be clinically assessing when undertaking a consultation. Risk assessments available clearly considered prescribing activity. This included inclusion and exclusion criteria and age restrictions. They also set out a need to check people's NHS Summary Care Record (SCR) and a need to verify medical conditions before supplying medicines for long-term conditions. Risk assessments also provided information about when to refer a person to a GP. The SI discussed how learning from peers had informed risk management. For example, following a conversation with a pharmacist independent prescriber, the pharmacy had decided not to prescribe propranolol due to the higher-risk nature of the medicine.

People accessing the pharmacy's prescribing services had their identity checked through an identity checking service. In all cases it required people to provide consent for their SCR to be accessed and for information to be shared with their regular prescriber. 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 and would then issue an electronic private prescription if a supply was deemed appropriate. The NIP explained how they corresponded with people via telephone or email if they required further information. For example, if information was missing from the SCR or if there was no SCR in place, such as for people residing in Scotland and Wales who accessed the service. The NIP provided a summary of the consultation on the private prescription and explained they kept more detailed notes of the consultation on their own internal record. But examples of documentation associated with these internal records were not provided. The pharmacy had not completed any clinical audits or prescribing reviews since launching its services. This had missed opportunities to identify situations where the team was not following the pharmacy's own policies. For example, the pharmacy had policies associated with maximum quantities and dispensing frequencies. These were designed to ensure people were not over ordering. But an example was seen where a person had received a repeated supplies of a P medicine containing opioid painkillers shortly after their first order. The pharmacy team investigated these supplies and acknowledged its system had not detected multiple accounts created by a person. This meant there was a risk of the pharmacy supplying medicines subject to abuse, misuse, and overuse as the necessary safeguards to prevent this were not in place. One example of two codeine-based medicines being supplied within the same transaction was also seen. This appeared to be a one-off error. Consultations associated with prescribing treatments for weight loss did not independently verify the weight beyond the information provided within the questionnaire. This meant there was a risk of people receiving medicines that may not be appropriate for them. The pharmacy had a general safeguarding procedure. But this did not consider the risks associated with prescribing online pharmacy services. And despite team members having completed safeguarding learning in previous roles they had not received training relating to specific risks associated with providing pharmacy services at a distance.

The pharmacy had procedures for managing mistakes made during the dispensing process. The superintendent pharmacist (SI) explained the pharmacy had not been alerted to any mistakes found after a medicine had been supplied to a person, known as a dispensing incident. The pharmacy used technology to support it in dispensing medicines. Its patient medication record (PMR) system prompted team members to scan medicines during the dispensing process. Any mistakes made at this stage were corrected before moving on with the dispensing process. But the team had not taken the opportunity to record these near misses. The SI stated that mistakes found during the accuracy check of a medicine would be recorded on an electronic near miss record. The SI could not recall such a mistake and no records had been made 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. A team member provided some examples of how feedback had been used to inform the packaging requirements of specific medicines.

The pharmacy had current indemnity insurance. The NIP stated they had their own indemnity insurance arrangements that covered their prescribing. But the pharmacy did not keep a copy of this insurance and evidence of this was not seen. There was no responsible pharmacist (RP) notice displayed, this was rectified immediately with a notice showing the correct details of the RP on duty. The SI had been the only RP working at the pharmacy. But the sign-out times of the RP in the RP record did not reflect the hours of operational activity. This was because the RP was signing out of the record when the NHS contractual hours ended each day, rather than when activity ceased. The pharmacy generally maintained its controlled drug (CD) register in accordance with legal requirements. But it did not routinely record the address of the wholesaler when entering receipt of a CD. The SI completed regular balance checks of stock medicines against the balances recorded in the register. The pharmacy held records of the private prescriptions it dispensed in an electronic record. The sample of the record

examined complied with legal requirements. The pharmacy held people's confidential information securely on password protected computers. And 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 people to carry out its services. It reviews it staffing levels and skill mix to help ensure they remain appropriate for the level of activity carried out. Pharmacy team members feel supported in their roles, and they know how to raise a concern at work.

Inspector's evidence

The pharmacy team had been struggling to cope with the volume of the work it was receiving since the recent increase in demand for its NHS services. In response to this it had very recently employed a delivery driver, a qualified dispenser, and a pharmacy technician. The SI was the RP on duty during the inspection, they were supported by a company director who worked in a customer service role, a qualified dispenser, and a dispatch assistant. The day of inspection was the dispenser's first day of employment. They had worked some locum shifts prior to joining the team and were familiar with the pharmacy's systems and ways of working. 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 SI shared plans to enrol the dispatch assistant on GPhC accredited learning to support them in their role. They did not currently complete any dispensing tasks and had received on-the-job learning associated with their role. A discussion highlighted the need to ensure the delivery driver was also enrolled on accredited learning within three months of commencing their role in line with GPhC guidance. The dispenser had discussed the opportunity to engage in further training to support their career progression when joining the team. The SI was currently training to be an independent pharmacist prescriber to support them in their role. The NIP was experienced and worked within roles in the NHS where they prescribed regularly. They verbally provided examples of courses they had completed to keep their knowledge up to date. These included learning associated with managing a range of clinical conditions. But the pharmacy had not asked for training records when employing the prescriber. The NIP confirmed they had provided these records to the pharmacy shortly after the inspection. The pharmacy did not set targets or incentives for any of its services. The NIP was empowered to use their professional judgment when prescribing. And there was evidence of rejected orders when the NIP felt a supply was not appropriate.

The pharmacy had a whistleblowing policy and its team members understood how to raise concerns at work. A team member explained they felt confident in asking questions at work and felt supported in their role. Pharmacy team members generally communicated through daily conversations. There was a focus on inducting team members and as such conversations generally related to the pharmacy's processes. The NIP worked remotely from the pharmacy. Communication between the NIP and pharmacy was generally via email. They were available to answer queries from the pharmacy team in a timely manner. The pharmacy's prescribing policy referred to a direct channel of communication through a secure web-based chat programme. But this had not been implemented.

Principle 3 - Premises **Standards not all met**

Summary findings

The pharmacy's website allows people to choose a treatment before starting a consultation with a prescriber which is not in line with GPhC guidance. And it contains information that is inaccurate and misleading. The pharmacy premises are adequately maintained and they are safe and secure.

Inspector's evidence

The pharmacy premises were secure from unauthorised access. They were clean and well maintained. Air conditioning regulated the temperature of the pharmacy and lighting was bright throughout the premises. Hand washing sinks were appropriately equipped with soap and towels. 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 healthcare related items, medicines, and devices. Work bench space for dispensing activities was limited. Due to the recent increase in NHS workload the team was observed holding some picked medicines in stacked baskets on the dispensary floor. This was not ideal, but the baskets were positioned in a way which avoid the risk of trip or fall.

People accessed the pharmacy's services through its website. The website allowed people to start a consultation from both a conditions page and from pages providing information about individual prescription-only medicines (POMs). And some pages providing information about POMs included inappropriate wording such as 'Buy' followed by the name of the medicine. The SI stated that people clicking on a 'start consultation' button on the POM pages should be sent back to the conditions page to start the consultation process. But the consultation automatically loaded from the POM pages and as such this was contrary to GPhC guidance as people could select their preferred treatment before starting a consultation with a prescriber. 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. It informed people they could click on the registration number of its prescribers to view registration information about them. But this link did not work, and an independent pharmacist prescriber (PIP) listed on the website had not worked for the pharmacy for some time.

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

Summary findings

The pharmacy does not manage all of its services safely. It does not consistently confirm people's diagnosis and verify information provided before prescribing medicines for long-term conditions and medicines requiring ongoing monitoring. And it does not ensure the information within all of its consultation questionnaires is relevant to the medical condition being treated. The pharmacy does not follow its own processes by informing people's usual prescriber about the medicines prescribed through the service. Taken together, these increase the risk that the pharmacy supplies prescription medicines to people which are not clinically appropriate, and people's conditions might not be properly monitored. The pharmacy does not store all of its medicines as required by law, and its systems do not ensure access to these medicines is controlled by a pharmacist. It does not have the necessary processes in place to manage waste medicines safely. The pharmacy 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. The private prescribing service required people to complete a consultation questionnaire. The team explained a similar process was required when people wanted to purchase a P medicine. But on the day of inspection the website was being updated and consultation questions associated with P medicines were not displaying. A discussion highlighted risks associated with making changes to live web pages which remained accessible to people. Immediate action was taken following this risk being highlighted and checks later in the day confirmed the consultation questions were loading as intended. The website contained brief information about each condition it prescribed treatment for. And people could read information about each treatment option. Some information on the website required updating. For example, the consultation questionnaire informed people their answers would be reviewed by a GPhC accredited prescriber, but the pharmacy currently used a NIP who was registered with the Nursing and Midwifery Council. Due to having a nurse prescriber the SI was informed of the need to make independent checks associated with the need to register the prescribing service with the Care Quality Commission.

The pharmacy confirmed the identity of people using the prescribing service via a third-party identification checking service. It provided details of the service it used on its website. People were asked to consent for information about the treatment provided by the pharmacy to be shared with their regular prescriber. And they were informed that some medicines could not be prescribed unless consent was provided. But it did not have any information about which medicines consent was mandatory for. And despite consent being given the pharmacy did not share prescribing information with a person's regular prescriber. It instead offered a template letter to people to provide to their prescriber. An overarching prescribing guideline indicated prescribers should generate this letter and the pharmacy team should send it to the regular prescriber. But this process was not followed. 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 chronic conditions.

The majority of prescribing was for weight loss medicines, steroid creams and a range of medicines used to treat chronic conditions. A review of a questionnaire template found a questionnaire for the weight loss service asked people about their use of a potent steroid cream and whether they were experiencing a current psoriasis flare up. This meant the prescriber would not have appropriate information on which to base a prescribing decision. There was no evidence of prescribing decisions made based on this questionnaire. A sample of consultation summaries examined found examples of medicines being supplied following verifying a person's medical condition and current medicine regimen. For example, this was seen in consultation summaries where asthma treatment was provided. And the NIP had requested photographs prior to prescribing treatment for psoriasis. But there were also multiple examples of summaries seen which did not verify the person had a medical condition. For example, a person received a years' supply of levothyroxine but there were no documented blood tests, and the SCR did not show the person had received the medicine before. The consultation summary associated with this supply stated the person had been diagnosed with the condition and was currently unable to make a GP appointment. It was not clear how this information had been independently verified and the NIP did not provide the internal consultation notes when provided with an opportunity to do so. The prescriber nor the pharmacy routinely checked blood test results as part of any ongoing monitoring processes. Other examples relating to non-verification of medical information included prescriptions for weight loss medicines which solely relied on information people provided within the consultation questionnaire. The NIP explained that orders from people with a low body mass index (BMI) were rejected and repeat orders required the BMI to be updated to help ensure supply was appropriate. But the pharmacy had no way of identifying if people updated information within the questionnaire prior to submitting it. For example, if people went back to change the answers they provided when completing the questionnaire. The NIP explained they had the autonomy to make prescribing decisions. And they provided an example of referring a person to their GP after they deemed it was not safe to prescribe HRT. There was evidence of rejected orders both relating to the prescribing service and the sale of P medicines. And few repeat transactions were seen in the sample of records relating to both services.

The team used the pharmacy's patient medication record (PMR) system to support it in completing a range of checks during the dispensing process for both NHS and private prescriptions. The process followed saw the RP complete the clinical check of the prescription at the beginning of the dispensing process, the PMR then produced a picking list of medicines required to fill a prescription. A team member individually scanned these medicines to produce dispensing labels. The SI described how using the barcode scanning features helped to significantly reduce the risk of a mistake occurring during the dispensing process as the PMR would not produce a label if the wrong medicine was scanned. The pharmacy used the PMR to support it in supplying medicines in multi-compartment compliance packs. This included producing medicine regimen and recording changes on the PMR. A sample of compliance packs contained supportive information to help a person take their medicines. The pharmacy supplied patient information leaflets when supplying medicines. 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. The pharmacy had invested in specific packaging designed to maintain the cold chain when supplying medicines requiring refrigeration. It sent these through a 24-hour tracked service. But it had not carried out any audits to confirm the cold-chain was maintained throughout the packages journey. It had considered timelines associated with dispensing and postage of these medicines and as such did not dispense them on a Friday. The pharmacy had some information to support ongoing monitoring checks associated with the NHS prescriptions it dispensed. This included information about the checks associated with supplying oral retinoids. But there was no supportive information available about the valproate pregnancy prevention

programme (PPP). The SI understood the checks associated with the programme and explained the pharmacy had not dispensed to a person in the at-risk group to date. A discussion highlighted the need to have supportive information available including both the patient and healthcare professional guide to the PPP.

The pharmacy obtained its medicines from licensed wholesalers. It stored them in an orderly manner on shelves throughout the dispensary. Medicines requiring cold storage were held in a medical fridge. It kept a record of fridge temperatures which were seen to be within the correct range. The pharmacy did not store its CDs as required. Team members checked expiry dates of medicines during the dispensing and supply process. But the pharmacy did not have an established regular date checking procedure. 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 he had taken medicine waste to another pharmacy on the rare occasion this was needed. A discussion highlighted the need for the pharmacy to have its own system to manage waste medicines itself. The pharmacy received details of medicine alerts by email. It kept an audit trail of any alerts and actions taken by the pharmacy.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment and facilities it needs to provide its services. It maintains its equipment to ensure it remains in safe working order. And its team members use the equipment appropriately.

Inspector's evidence

Pharmacy team members had electronic access to appropriate 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. Electrical equipment was in good working order and was visibly free from wear and tear. The pharmacy's computer systems were password protected and team members used NHS smart cards 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.