General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Live Well Pharmacy, 1 Acre House Avenue, Huddersfield, West Yorkshire, HD3 3BB

Pharmacy reference: 9011473

Type of pharmacy: Internet / distance selling

Date of inspection: 29/11/2023

Pharmacy context

The pharmacy is in a residential area in the suburbs of Huddersfield. It has a distance selling NHS contract. Pharmacy team members dispense NHS prescriptions and deliver them to people's homes. They provide medicines to some people in multi-compartment compliance packs. And they provide medicines to people living in care homes and nursing homes. The pharmacy provides a private prescribing service to people, via its website www.usmen.co.uk, to help treat erectile dysfunction and male hair loss.

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 suitable risk assessments for the services and the medicines it supplies. This includes for medicines being used outside of the manufacturer's product license.
		1.2	Standard not met	The pharmacy does not properly audit the safety and quality of its private prescribing service. The audit it has completed does not provide enough detailed, meaningful information for pharmacy team members to use to help improve the safety and quality of its service.
		1.6	Standard not met	The pharmacy does not keep complete and accurate records for its private services and its prescribing consultations, to help pharmacy team members make effective clinical assessments.
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 for its private services does not meet current guidance. The way the pharmacy has the website organised means there is a risk that people might not always receive the most appropriate treatment.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy's private prescribing service generates prescriptions that are not legally valid. And the pharmacy dispenses and supplies medicines against these invalid prescriptions.
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 fully assess and manage the risks of providing its private services to people. It does not have an adequate risk assessment and procedure for these services. And it does not actively monitor its private services or complete adequate records of prescribing to ensure it provides these services safely. Pharmacy team members follow suitable written procedures to help provide its NHS services safely. And it keeps the records it should for these services. Pharmacy team members generally understand how to protect vulnerable people. And they keep people's private information secure.

Inspector's evidence

The pharmacy provided a private prescribing service to treat hair loss and erectile dysfunction in men. It employed a pharmacist independent prescriber (PIP) who prescribed from a small formulary of medicines for each condition. People accessed the service via the pharmacy's website, www.usmen.co.uk, and the service had been operating fully since April 2023. In order to request a prescription, people completed a questionnaire about their symptoms. Their responses were then screened by the PIP, who determined whether or not it was appropriate to prescribe for the person. If it was, they generated a private prescription that was dispensed by the pharmacy.

People accessing the pharmacy's private prescribing service completed a questionnaire. The questionnaire asked key questions to help determine their symptoms, the person's medical history, and whether they had tried anything to treat their symptoms already. And the PIP used the information provided to make their prescribing decision. They also sometimes used other information that might be available to the pharmacy by accessing the person's NHS Summary Care Records (SCR) or information already held by the pharmacy from previous dispensing. Some of the information necessary to help the PIP make effective prescribing decisions about each condition was collected as part of the questionnaire people were asked to complete. But the questionnaire allowed people to change their responses in order to progress through the pharmacy's screening process. The prescriber and pharmacy team members could not identify when this happened and so could not use this information as part of their decision to prescribe.

The pharmacist owner had documented a general risk assessment (RA) for the pharmacy's prescribing service. The risk assessment considered some general risks of providing a prescribing service to people at a distance via the internet, such as verifying people's identity, screening of the information people provided, and some broad criteria to help determine safe prescribing. The documented information was brief, but it provided details about the risks the pharmacy had identified and the mitigations they had implemented to help reduce risks. But the RA lacked detail of specific risks for each condition prescribed. So, it missed opportunities to identify risks associated with prescribing these treatments and managing the risks by, for example, setting maximum quantities and frequencies of prescribing.

One of the medicines on the pharmacy's prescribing formulary was an unlicensed topical medicine to treat hair loss. The pharmacy had used information available from limited clinical trials to determine the strength of the medicine they were comfortable prescribing and supplying to people. It obtained the product from a specials manufacturer that was regulated by the Medicines and Healthcare products Regulatory Agency (MHRA). And it provided people with information about the products unlicensed nature, and what this meant, on its website. But the pharmacy did not have a documented risk

assessment or a prescribing policy for prescribing unlicensed medicines to people. And they did not provide people with further information about how to safely use an unlicensed medicine when they supplied the product at the end of the dispensing process.

The pharmacy had an overarching standard operating procedure (SOP) in place for its private prescribing service. The SOP provided basic information to help team members provide the service. The pharmacy had SOPs in place for the other services it provided to people. These had been implemented in August 2022 and were due for review in August 2024. Pharmacy team members had signed to confirm they had read and understood the written procedures. The pharmacy owner had completed a checklist that considered some of the risks of providing services to people from a distance. They had made notes to confirm their findings and any action they had taken. But the checklist was not complete and did not consider the pharmacy's private prescribing service.

Following the inspection, the pharmacy owner provided the inspector with a copy of an audit checklist. The audit was a brief self-audit completed by the PIP. It provided assurances that the pharmacy had reviewed some of their prescribing processes. But it lacked detail, such as the number of people who had had their prescribing journey reviewed and the elements of prescribing that had been checked. It did not provide clear conclusions about the pharmacy's findings or specific actions to improve the safety and quality of the service. The pharmacy did not have a clear plan for ongoing audit of the private prescribing service.

Pharmacy team members explained that they highlighted and recorded near miss errors. There was an SOP to help them do this effectively. But during the inspection, they could not provide records of any near miss errors that had happened after July 2022. Team members explained they discussed errors and why they might have happened and made changes to help prevent mistakes happening again. One example was separating Depakote and Epilim on the pharmacy's shelves to help prevent picking errors. Lack of error records meant that pharmacy team members were unable to regularly review errors to identify patterns of mistakes to help prevent recurrences and aid future learning. The pharmacy had a system in place to manage and record dispensing errors, which were errors identified after the person had received their medicines. There was a written SOP to help team members manage dispensing errors effectively. The owner explained they had made dispensing errors. But during the inspection, they could not provide any records of the errors that had been made. This meant the inspector was unable to assess the quality of the pharmacy's response to dispensing errors at this inspection. The owner gave a clear explanation about how they would manage and record an error if it occurred.

The pharmacy had a documented procedure to deal with complaints handling and reporting. It advertised a complaint's procedure to people on both of its websites, www.livewellpharmacy.co.uk and www.usmen.co.uk. The pharmacy had up-to-date professional indemnity insurance in place. It maintained a responsible pharmacist record which was complete and up to date. It kept controlled drug (CD) registers electronically, and these were in order. The pharmacy kept running balances in all registers. These were audited against the physical stock quantity approximately every three months. The pharmacy kept accurate private prescription and emergency supply records. And the pharmacy also kept a register of CDs returned by people for destruction.

The pharmacy did not have a consistent system in place to enable the PIP to comprehensively record their prescribing consultations. The pharmacy kept records of each person's responses to the online questionnaire. But the PIP did not keep records of their clinical decision-making process that led to a clinical diagnosis and their decision to prescribe or not for each person making a request. And there were no records made of any further information provided to people after prescribing had taken place. The PIP sometimes recorded clinical queries in a notebook. And sometimes, they made a note of a

rejected order on the prescription that had been generated. Two recent examples were requests from women to purchase medicines to treat erectile dysfunction. But these methods of keeping notes meant the information would be difficult to retrieve and use again in the future.

The pharmacy kept sensitive information and materials securely in the pharmacy. Team members used a shredder to destroy confidential waste. The pharmacy had a documented procedure to help pharmacy team members manage sensitive information correctly. Team members explained how important it was to protect people's privacy and how they would protect confidentiality.

The pharmacy had an SOP to help team members manage concerns about vulnerable people accessing its private services. But it did not have a documented procedure to help them manage concerns about children and vulnerable adults accessing its NHS services. A pharmacy team member gave some examples of signs that would raise their concerns when delivering NHS services. And they explained how they would refer any concerns to the pharmacist. The team also explained how they would use the internet to find the most up-to-date local safeguarding contacts to refer their concerns to. And they had completed formal safeguarding training in 2022.

Principle 2 - Staffing ✔ Standards met

Summary findings

Pharmacy team members have the right qualifications for their roles and the services they provide. They complete some training ad-hoc to keep their knowledge up to date. And they feel comfortable discussing ideas and raising concerns.

Inspector's evidence

During the inspection, the pharmacy team members present were the pharmacist owner and a qualified dispenser. In addition to this, the pharmacy employed two part-time delivery drivers and a part-time pharmacist prescriber. The superintendent pharmacist also worked at the pharmacy occasionally. Pharmacy team members completed ad hoc ongoing learning, which included online training modules, reading various materials, and team members also regularly discussed learning topics informally with each other. The pharmacist provided information or signposted them to relevant materials and resources to help answer their questions. Some recent examples of completed training had been e-learning modules about suicide awareness and antimicrobial stewardship. The pharmacy did not have a formal appraisal process. Team members explained they would raise any learning needs with the pharmacist informally. And they were confident the pharmacist would support them to find the information they needed. The pharmacist independent prescriber (PIP) had recently provided the pharmacy owner with a statement of competence to confirm their training and ongoing learning. This gave the owner assurances that the PIP was competent to prescribe for the conditions covered under the pharmacy’s online service.

Team members explained how they would raise professional concerns with the owner or superintendent pharmacist (SI). They felt comfortable raising concerns. Team members also felt comfortable making suggestions to help improve the pharmacy's ways of working. They were confident that their concerns and suggestions would be considered, and changes would be made where they were needed. One recent example following discussions had been reorganising the layout of the pharmacy to provide more space for storage and preparing prescriptions. The pharmacy did not have a formal whistleblowing policy. Pharmacy team members said they would raise any concerns anonymously with GPhC or the NHS.

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

Summary findings

The pharmacy's website for its private services is organised in a way which means there is a risk people may not always receive the most appropriate treatment. The pharmacy's premises is clean and properly maintained. And they provide a suitable space for its services.

Inspector's evidence

The pharmacy was in a building that formed part of a residential property, and it could not be directly accessed by the public. It was properly secured, and pharmacy team members controlled access to the pharmacy to help prevent unauthorised access during working hours. The pharmacy had various rooms that team members used for varying purposes including office space and storage. The pharmacy was tidy and well maintained. It had defined areas for dispensing and checking and there was a defined workflow in operation. The pharmacy's floors and passageways were free from clutter and obstruction. It had a clean, well-maintained sink used for medicines preparation. There was a toilet, a sink with hot and cold running water and other facilities for hand washing. Heat and light in the pharmacy was maintained to acceptable levels. The overall appearance of the premises was professional and suitable for the services being provided.

The name and address of the pharmacy, and the details of its GPhC registration were displayed on the website for its private prescribing service, www.usmen.co.uk. The website also provided the name and registration information of the superintendent pharmacist, the pharmacist owner and the pharmacist independent prescriber who prescribed medicines for people using the online service. The website provided very little information about the conditions the pharmacy was able to treat. Instead, the focus of the information was on the products and medicines the pharmacy was able to provide. And the pharmacy provided comprehensive information to people about the medicines available. People could start a consultation for each condition by clicking a button on the page for each condition. But people were also able to start a consultation directly from the pages detailing the treatments. They were able to select their preferred medicine before completing the prescriber's consultation questionnaire. And this indicated that the person and not the prescriber selected the treatment for the person's condition. This was not in accordance with GPhC guidance and meant that people may not always receive the most suitable medicines to treat their condition.

One of the medicines offered by the pharmacy was an unlicensed topical medicine to treat hair loss. There were several areas of the pharmacy's website that made unsubstantiated claims about the effectiveness of the unlicensed medicine and its efficacy in treating conditions. The pharmacy's website also contained misleading wording relating to the way it was regulated.

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

Summary findings

The pharmacy generates and dispenses prescriptions from its private prescribing service that are not legally valid and are missing key information. Overall, it suitably manages the delivery of its services safely. And it generally stores and manages its medicines appropriately. The pharmacy's services are easy for people to access. And it has processes to help people understand and manage the risks of taking some higher-risk medicines.

Inspector's evidence

People did not visit the pharmacy. They communicated with the pharmacy by telephone and email. The pharmacy had two websites, www.livewellpharmacy.co.uk and www.usmen.co.uk, where it provided its contact details and information about its services. Pharmacy team members could provide large print labels for people with visual impairment. They explained how they would communicate in writing with people with a hearing impairment.

When people placed an order with the pharmacy via their prescribing service, the pharmacy's electronic system generated an order. Pharmacy team members printed the order, and the pharmacist independent prescriber (PIP) used the information to make their clinical and prescribing assessment. If they were satisfied with the information and were happy to prescribe the medicine, they signed and dated the order form. And this constituted the private prescription for the order. But in several examples seen, these private prescriptions were not legally valid. They often did not display key information legally required, for example the strength and dosage form of the medicine and the dose prescribed by the PIP. None of the prescriptions seen displayed the address of the prescriber. Once a prescription had been generated, pharmacy team members assembled, labelled, and dispensed the prescriptions in the same way they prepared and dispensed for their NHS services.

Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing for both NHS and private prescriptions. This was to maintain an audit trail of the people involved in the dispensing process. Team members used baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacy supplied medicines to people in multi-compartment compliance packs when requested to help them take their medicines correctly. It attached backing sheets to the packs, so people had written instructions of how to take their medicines. But team members did not include descriptions of what the medicines looked like on the backing sheets. So, people may have difficulty identifying each medicine in their pack. They provided people with patient information leaflets about their medicines every three months, instead of at each dispensing. Pharmacy team members documented any changes to medicines provided in packs on the person's electronic patient medication record (PMR).

The pharmacist owner counselled people receiving prescriptions for valproate if appropriate. And they checked if the person was aware of the risks if they became pregnant while taking the medicine. They advised they would also check if they were on a pregnancy prevention programme and taking regular effective contraception. The pharmacy had stock of some information materials to give to people to help them manage the risks of taking valproate, and team members were aware of the need to dispense valproate in their original manufacturer's packs. The owner had completed an audit of people who the pharmacy provided valproate to, to ensure people had received the correct advice.

The pharmacy delivered medicines to people, either by using its own delivery drivers or by using a national courier service. And it recorded the deliveries it made. When the pharmacy used their own delivery drivers, the driver left a card through the letterbox if someone was not at home when they delivered. The card asked people to contact the pharmacy. Deliveries made further afield using the courier were tracked and people were provided with the tracking information so they could monitor their delivery. If someone was not at home when the delivery arrived, the courier returned the package to the local delivery office and re-attempted the delivery the following day. If the re-attempt also failed, the medicines were returned to the pharmacy for the team to investigate.

The pharmacy obtained medicines from licensed wholesalers. And it used a manufacturer to supply its unlicensed topical hair loss treatment that was regulated by the MHRA. It had disposal facilities available for unwanted medicines, including CDs. Team members monitored the minimum and maximum temperatures in the pharmacy's fridge each day and recorded their findings. The temperature records seen were within acceptable limits. Pharmacy team members checked medicine expiry dates every three months. But they did not record that they had completed these checks to help prevent sections of the pharmacy being missed. They highlighted and segregated any short-dated items up to six months before their expiry. After a search of the shelves, no out-of-date medicines were found. Pharmacy team members responded to manufacturers alerts and recalls. They kept records of the recalls they had received and any action they had taken to remove affected medicines.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the necessary equipment available for the services it provides. It manages and uses its equipment in ways that protect people's confidentiality.

Inspector's evidence

The pharmacy had the necessary equipment to restrict access to the premises. And it had the equipment it needed to provide the services offered. The resources it had available included the British National Formulary (BNF), the BNF for Children, various pharmacy reference texts and use of the internet. It had a shredder available to destroy its confidential waste. It kept its computer terminals in the secure pharmacy, and these were password protected. It had a set of clean, well-maintained measures available for medicines preparation.

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.