General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Certified Health Ltd, Unit ID 47 Globe Mill, Bridge Street, Slaithwaite, Huddersfield, West Yorkshire, HD7 5JN

Pharmacy reference: 9011877

Type of pharmacy: Internet / distance selling

Date of inspection: 06/12/2024

Pharmacy context

The pharmacy is in a business centre in Slaithwaite, near Huddersfield. It dispenses private prescriptions for a small range of unlicensed topical and oral medicines following a private online consultation. People access the service to help treat hair loss via its website, www.unthin.co.uk. The pharmacy does not have a contract to provide NHS services and people do not access the pharmacy premises directly.

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 properly identify and manage all the risks with its services, including for supplies of its unlicensed treatments. It does not have written procedures, policies and risk assessments for all its activities. And it doesn't have adequate clinical governance arrangements to manage safe prescribing and supply of its medicines.
		1.2	Standard not met	The pharmacy does not meaningfully audit and monitor the quality and safety of its services, including auditing prescribing against its policies. And it does not audit and monitor the supplies it makes against its policies.
2. Staff	Standards met	N/A	N/A	N/A
3. Premises	Standards not all met	3.1	Standard not met	Some parts of the pharmacy's website appear transactional in nature, suggesting to people they can buy treatments by adding to their cart. And it is not always clear they are entering into a consultation process with the prescriber. The website makes unsubstantiated medicinal claims about unlicensed medicines.
4. Services, including medicines management	Standards not all met	4.2	Standard not met	The pharmacy does not have adequate safeguards to ensure the safe and effective delivery of its services. It does not always have sufficient information or use the information it has to ensure people receive medicines suitable for them to use.
		4.3	Standard not met	The pharmacy does not label its dispensed medicines with enough information to comply with current law.
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 adequately assess and manage all the risks of providing private services and unlicensed medicines to people. And it does not have the written procedures and policies it needs for these services. It does not have suitable clinical governance arrangements for prescribing and supplies of medicines. And it does not actively review and monitor the quality of its services to ensure it provides them safely. The pharmacy keeps the records it needs to by law and keeps people's confidential information secure. Team members understand how to help protect vulnerable people accessing services.

Inspector's evidence

The pharmacy provided private services to people via its website, www.unthin.co.uk. It provided a range of topical treatments, including unlicensed prescription only medicines (POMs), and an oral unlicensed medicine to treat hair loss. The pharmacy did not have a contract to provide NHS services. And the current superintendent pharmacist (SI), who was also the service's prescriber, had been in post since September 2024.

The pharmacy did not have any documented risk assessments for its prescribing services or the medicines it provided. All the medicines the pharmacy provided were unlicensed medicines manufactured by a licensed specials manufacturer on the pharmacy's behalf. The pharmacy had some information available about some of the medicines it used in its products. But the information was based on the licensed versions of these medicines, which the pharmacy did not supply. And there was no evidence available about how the pharmacy's prescriber, who was also the superintendent pharmacist (SI), had determined key elements of their prescribing frameworks. This included the dose prescribed, the quantities provided to people, the frequency people received prescriptions, and when requests should be rejected. Team members had documented assessments of some operational risks shortly after the pharmacy had opened in 2021, such as health and safety and security. Although there were no documented risk assessments the pharmacy had made some assessment of the risks of supplying unlicensed medicines to people. The pharmacy notified people that their medicines were unlicensed in various areas of the website, and in materials sent to people when they received their medicines. And they explained to people what an unlicensed medicine was and its implications.

The pharmacy did not have documented policies in place to help pharmacy team members manage the safe prescribing and supply of its medicines. This meant there were no guidelines for the SI to follow when prescribing the range of products stocked. And no guidelines for the pharmacy team to use to check prescribing was safe and clinically appropriate. This included the signs and symptoms of the presenting condition, information to aid a differential diagnosis, inclusion and exclusion criteria for receiving the medicine, and the necessary records required to support safe prescribing. The SI had access to some guidelines to help support safe prescribing of finasteride and topical minoxidil as individual medicines. But the guidelines were based on the licensed versions of these medicines, which the pharmacy did not supply, and not the specific products and unlicensed medicines being provided by the pharmacy.

The pharmacy had some standard operating procedures (SOPs) in place to help pharmacy team members manage the risks to the dispensing parts of its services. The pharmacy's previous SI had reviewed the SOPs in 2023. And they were due to be reviewed again in 2025. All pharmacy team

members, including the SI, had signed to confirm they had read and understood the SOPs since the last review, or since they had started working at the pharmacy. But there were several areas of the business that did not have a documented SOP or policy. These included written procedures for supplying unlicensed medicines to people, recording information to support clinical decisions when prescribing and supplying medicines, for managing and recording clinical interventions and for managing ongoing audit and monitoring of the pharmacy services and the medicines it supplied to people. To use the pharmacy's website, people were required to register an account with the website. But there was no SOP or policy available to demonstrate how people registered or the information they were asked to provide. Or whether the pharmacy made any further checks to confirm people's identity.

The pharmacy did not have any systems to regularly audit prescribing, or to highlight areas that were appropriate for the pharmacist's intervention. And without prescribing and dispensing policies, it was difficult for the pharmacy to conduct these audits effectively. The pharmacy had a process in place to review people who had been receiving treatment for 12 months. The review asked people to respond to a set of questions to determine whether their circumstances had changed, such as regular medicines they were taking or if their symptoms had changed. If there had been any changes, they were asked to complete the pharmacy's original prescribing questionnaire again, for review by the pharmacist. If there had been no changes to the questions asked, their subscription was automatically renewed for another 12 months, without any intervention from the pharmacist. There was no documented information available to determine why the review period had been set at 12 months for people. Several areas of the pharmacy's website stated that people may start to experience changes within three to six months. But the pharmacy did not contact people before 12 months to check for efficacy or whether people were experiencing side effects of using their medicines.

The pharmacy did not have a process to seek consent from people to share information about the services provided with their usual NHS prescriber. The SI explained how the pharmacy's terms and conditions asked people to inform their GP of their treatment themselves. But they did not check that people had done so. This meant people's regular GP may not be aware of the treatment being provided by the pharmacy, especially if they presented at their GP with symptoms of declining mental health or to have tests on their levels of prostate specific antigen (PSA).

Pharmacy team members highlighted and recorded mistakes identified before people received their medicines, known as near misses, and dispensing errors, which were errors identified after the person had received their medicines. And there were documented procedures to help them do this effectively. Team members discussed mistakes and why they might have happened. And they gave some examples of changes they had made to help prevent isolated near miss errors from happening again, such as dispensing prescriptions for one product at a time to help prevent errors selecting the wrong product. The pharmacy had a process for responding to and recording dispensing errors. People would contact the pharmacy via email. And the dispenser would pass on any emails relating to errors directly to the pharmacist. There were no records of errors available. Team members explained this was because the pharmacy had not made a dispensing error since opening in 2021.

The pharmacy had a documented procedure to deal with complaints handling and reporting. It published contact information on its website. People also left reviews and ratings on the pharmacy's customer service system. Team members explained how they had changed the way the read people's emails after they had received feedback about not responding in full to someone's query. The pharmacy had current professional indemnity insurance in place. It maintained a responsible pharmacist record, which was mostly complete. It kept records of the private prescriptions it dispensed.

The pharmacy kept sensitive information and materials in restricted areas of the pharmacy. And team members shredded confidential waste. The pharmacy had a documented procedure in place to help

pharmacy team members manage sensitive information. But it did not reflect the pharmacy's operating model. Pharmacy team members explained how important it was to protect people's privacy and how they would protect people's confidentiality.

Pharmacy team members gave some examples of signs that would raise their concerns about vulnerable people using their services. And they had recently completed formal safeguarding training. They explained how they would discuss their concerns amongst the team. And they were aware of how to find information about key local safeguarding contacts by using the internet. The pharmacy did not have any specific procedures in place to help safeguard people using its services from various parts of the UK. Or procedures that were specific to its remote operating model.

Principle 2 - Staffing ✔ Standards met

Summary findings

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

Inspector's evidence

At the time of the inspection, the pharmacy team members present were the SI, who was also the pharmacy's prescriber, a qualified dispenser who was also the pharmacy's customer service representative, and the pharmacy owner who was also a trainee dispenser. The trainee was enrolled on the necessary qualification training to provide dispensing services to people. And the pharmacy's qualified dispenser was trained in customer service skills and was also enrolled in training to become an accuracy checking dispenser (ACD). Team members completed ongoing learning ad hoc by reading various materials and discussing topics with the pharmacist. A recent example had been training on two of the pharmacy's new primary systems to help improve their management of prescriptions and dispensing, and another for improved customer services. The SI explained they had undertaken learning to develop their knowledge of hair loss by reading primary literature sources, academic studies, and training courses relating to hair loss. And they had worked with people to treat hair loss in a previous role. They had also completed training in other areas of dermatology and to improve their consultation skills.

Pharmacy team members explained they would raise professional concerns with the SI or the pharmacy's owners, who worked closely with the pharmacy. They felt comfortable raising concerns and confident that concerns would be considered. Team members communicated with an open working dialogue during the inspection. They felt comfortable making suggestions to improve their ways of working. They explained how they had raised ideas with the owners since the pharmacy had opened about various elements of their service. And in response, the pharmacy's owners had carefully considered their suggestions, for example by improving packaging to help their medicines look more professional. Team members explained how they would contact the GPhC for advice if they had a concern they could not raise internally. The pharmacy also had a whistleblowing policy available for team members to use to raise their concerns anonymously.

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

Summary findings

Some areas of the pharmacy's website are organised in a way which means there is a risk people may not always receive the most appropriate treatment. And the way people obtain these treatments appears transactional. The pharmacy clearly informs people about the unlicensed nature of the medicines it supplies. But it makes unproven medicinal claims about these medicines on its website. And it does not make it clear to people about who is prescribing their medicines. The pharmacy's premises are clean, secure, and properly maintained. And it provides a suitable space for providing its services.

Inspector's evidence

The pharmacy's website, www.unthin.co.uk, provided people with a link to the pharmacy's GPhC registration, which also provided the pharmacy's name and address. The website provided the name and registration information of the superintendent pharmacist. But it did not always provide clear information to people about the need to provide information about their health, the need for a prescription, and who the pharmacy's prescriber was. The website provided comprehensive information about the conditions treated and the medicines and treatment plans available, including their unlicensed nature and what this meant.

Generally, the pharmacy's website was condition and consultation driven and there was information about completing an online questionnaire consultation before supply. And people were asked to add their chosen medicine or treatment plan to the cart and complete a financial transaction after they had completed a consultation questionnaire. But there were some areas of the pharmacy's website, accessed via certain menus, where people selected their chosen medicines or plan, and complete a financial transaction, with no information about completing a consultation questionnaire and no information about appropriateness of treatment being a decision made with the prescriber. And this was by use of wording such as "add to cart". This made parts of the pharmacy's website appear transactional and not driven by prescribing for a condition. The person selected the treatment for their condition from the website and it was not made clear that the medicine prescribed was the decision of the prescriber.

All the medicines offered by the pharmacy were unlicensed topical and oral medicines to treat hair loss. There were several areas of the pharmacy's website that made unsubstantiated claims about the medicinal effectiveness of the unlicensed medicines and their efficacy in treating conditions, including on the website's homepage.

The pharmacy was in a room in a building shared with another business, 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 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 were free from clutter and obstruction. Pharmacy team members had access to a clean, well-maintained sink. 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.

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

Summary findings

The pharmacy does not have adequate safeguards to ensure people always receive medicines which are suitable for them. The pharmacy does not label its dispensed medicines with key information and in accordance with the law. The pharmacy's services are accessible to people. Team members make adequate checks of medicines to make sure they are in date and suitable to supply. And they provide people with sufficient information about the unlicensed nature of the medicines they supply.

Inspector's evidence

People did not visit the pharmacy. They communicated with the pharmacy primarily by using the help@unthin.co.uk email address advertised on the pharmacy's website. The pharmacy's website provided contact details and information about its services. The dispenser explained they screened all emails that arrived in the help inbox. And they referred relevant emails to the pharmacist to consider and contact people by telephone if necessary. 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.

After registering with the pharmacy's website, people were asked to complete a questionnaire about their symptoms. And their responses provided information which could be used by the prescriber to inform their prescribing decisions. People were asked for information, including their date of birth, gender, and information about their medical history including other medicines they may be taking. There were no processes or safeguards embedded in the pharmacy's website consultation form that helped the pharmacy identify whether people had provided false or misleading information. All information provided was available for the prescriber to review. At the end of the questionnaire, the website asked people to choose a "preferred" product. The SI was asked what information was used to determine if the person's preferred product was suitable. They explained people usually received their chosen product, with little consideration of the information the person had provided in their questionnaire, unless the questionnaire's pre-set algorithms alerted a problem, such as someone who was taking another medicine that interacted, or they had described symptoms that did not match the types of hair loss the pharmacy was able to treat. An exception to this was when someone requested the daily oral capsules. The SI explained that if someone requested the capsules, they contacted them by telephone to ask them supplementary questions. And the questions provided the SI with further information and assurances about whether to prescribe, such as the person's mental health history in relation to finasteride. The SI recorded brief information about these supplementary questions on a paper form. There was no process in place to verify the information people provided in their questionnaire. Team members showed some records of interventions they had made. And records where people could not be contacted for their review and had not been provided with further medicines.

The private prescriptions dispensed by the pharmacy were generated electronically using the pharmacy's website. The SI was the only pharmacist working at the pharmacy. And they held the role of SI, prescriber, and responsible pharmacist (RP) simultaneously. If the SI chose to prescribe for a person, the prescriptions were printed, and they signed each prescription using a wet signature. Prescriptions were then dispensed by a dispenser and checked for accuracy by the SI. The prescriptions seen were complete and contained all the legally required information. The SI explained and demonstrated that

they usually had a mental break between prescribing and checking the prescriptions once they had been dispensed. And the breaks were often anywhere from 30 minutes to two days, depending on the workload and when the prescriptions had been dispensed. The SI did not always make comprehensive records of their consultations. Or the information they used to inform their prescribing decisions. They explained they sometimes telephoned people to seek further information before prescribing. And they sometimes made hand-written notes of information provided on the back of people's prescription. But they did not usually record these conversations on the person centralised electronic record, which meant records may not be available when completing future reviews or for other team members to look at. The pharmacist's clinical checks and prescribing decisions appeared basic made with little information outside of what someone had provided in their questionnaire. The pharmacist read people's responses to questionnaires. But relied mainly on the system's algorithms to determine their prescribing decisions. The SI also did not check the questionnaires when making repeat supplies of medicines, which had originally been considered by the pharmacy's previous prescribers. The SI explained people were often provided with the product they had requested, with little consideration of the person's individual needs or circumstances. This meant that the pharmacy could not be assured that the supplies it was making were safe and appropriate for each person.

The pharmacy used a manufacturer to supply its unlicensed topical hair loss medicines that was regulated by the MHRA. It received these liquid medicines in containers that had pre-printed information attached to the bottle. The information included most of the necessary legally required information for a dispensed medicine, including the strength and form of the medicine, the directions for use, the required cautionary and advisory warnings. and the name and address of the pharmacy. But it did not contain information about the person's name or the date the medicine was dispensed. This information was included on a dispensing label that pharmacy team members printed and attached to a card that accompanied the medicine in its box. This meant that the medicines the pharmacy provided were not labelled in accordance with the law.

Pharmacy team members maintained an audit trail of the people involved in the dispensing process on the dispensing label. They used baskets throughout the dispensing process to help prevent prescriptions being mixed up. The pharmacy packaged medicines in branded boxes, which were sealed with a shipping label showing the person's details. The box also contained a QR code on the inside, which people could scan to access a patient information leaflet about their medicines. The pharmacy delivered medicines to people using a national courier service. Deliveries 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 dispenser explained their understanding about how the courier returned the package to the pharmacy for the team to investigate. They explained undelivered medicines were returned to the pharmacy within 14 days, where they were immediately destroyed. The pharmacy did not supply or deliver any medicines that required cold storage.

Pharmacy team members checked medicine expiry dates at least once a month, sometimes more. And they recorded their checks. Medicines with less than three months were rotated so they could be used first, before being segregated and destroyed if they had less than a month's expiry left.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the equipment it needs to provide its services safely. It maintains its equipment properly, so it is safe to use. And pharmacy team members manage and use the equipment in ways that protect people’s confidentiality.

Inspector's evidence

The pharmacy had the equipment it needed to provide the services offered. It had various reference resources available, and use of the internet. It had a shredder to destroy its confidential waste. It kept its password-protected computer terminals and bags of medicines waiting to be delivered in the secure areas of the pharmacy, where people's private information was protected.

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.