General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: The Family Pharma Ltd, Unit 6, Acorn Business Park, Airedale Business Centre, Skipton, North Yorkshire, BD23 2UE

Pharmacy reference: 9011239

Type of pharmacy: Internet / distance selling

Date of inspection: 13/06/2024

Pharmacy context

The pharmacy is in a business park in Skipton. It dispenses a small range of unlicensed topical medicines following a private online consultation. People access the service to help treat hair loss via its website www.densehairexperts.com. 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 unlicenced treatments. It does not have written procedures for all its activities and some procedures it does have are not relevant to way team members work. The pharmacy has an incomplete documented risk assessment which doesn't sufficiently identify all the key risks associated with providing its services. And it doesn't implement all the actions documented in the risk assessment.
		1.2	Standard not met	The pharmacy does not meaningfully audit and monitor the quality and safety of its services, including audits of prescribing against its prescribing policies. It does not audit and monitor the supplies it makes against its policies. And when it identifies improvements to the way the service operates it does not always act on this information.
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 does not clearly explain how its services operate, and it appears transactional in nature. People select a product before being asked to complete an online consultation for the prescriber. This means people may not always receive the most appropriate treatment. And the website makes unsubstantiated 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 attaches dispensing labels to its medicines, which do not contain its

Principle	Principle finding	Exception standard reference	Notable practice	Why
				address and so do not comply with current law. The labels on its stock medicine bottles do not always show the required details. They are often blurred or missing print such as batch number and expiry date of the medicine.
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 properly assess or manage all the risks of providing its private services to people. And it does not have adequate written procedures for these services. It does not actively review and monitor the quality of its services to ensure it provides them safely. The pharmacy keeps people's private information secure and team members generally understand how to help protect vulnerable people accessing services.

Inspector's evidence

The pharmacy provided private services to people via its website, www.densehairexperts.com. The pharmacy provided a range of topical treatments, including unlicensed prescription only medicines (POMs) and some vitamin supplements, to treat hair loss. The pharmacy did not have a contract to provide NHS services.

The pharmacy had standard operating procedures (SOPs) in place to help pharmacy team members manage its services. Some team members had read the procedures and signed to confirm their understanding when they were implemented in 2019. But the trainee dispenser present during the inspection had started working at the pharmacy approximately four months ago. And they had not read or signed the SOPs. The superintendent pharmacist (SI) had last reviewed the SOPs in 2023 and had identified several changes to make sure the SOPs aligned with the way activities were being undertaken in the pharmacy. But they had not implemented any changes to address their findings and make improvements. For example, they had identified that the SOP for preparing prescriptions was insufficient and did not align with the way the task was being completed by team members. But they had not made any changes to the SOP or the process to make sure team members were clear about the agreed, safest way to complete the task. There were several areas of the business that did not have a documented SOP. These included written procedures for supplying unlicensed medicines to people, 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. The pharmacy did not have a procedure for verifying people's identity who requested medicines via its website. And pharmacy team members did not know how the prescriber verified the identity of people they were prescribing to.

After choosing a product on the pharmacy's website and completing a checkout process, people were asked to complete a questionnaire about their symptoms. And their responses provided most of the information used by the prescriber to inform their prescribing decisions. People were also asked for other 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 prevent people from providing false or misleading information. Or from inputting information that made no sense into the form. All information provided was passed to the prescriber to review. At the end of the questionnaire, the website recommended people to choose a "preferred" product instead of the product they had chosen at first, which was a topical solution of minoxidil 5% and finasteride 0.1%. This may be confusing for people accessing

services. The SI was asked what information was used to recommend that product to people. They stated that the recommendation was based on a general assumption that the product was the most popular and suited most people's needs. And the assumption that the product achieved the most success. The SI admitted that when recommending the product, there was no consideration of the information the person had provided in their questionnaire, or the person's individual needs or circumstances.

The pharmacy had a documented risk assessment (RA) of their private service. The RA covered various elements of the service, including risks associated with the website purchasing process, identity verification, inappropriate prescribing decisions, and risks in the dispensing and delivery process. The RA detailed some risk mitigation strategies to help manage these risks. But there was evidence that these strategies had not been implemented. For example, the pharmacy stated it would implement robust identity verification processes requiring people to upload photo identification, that it would conduct regular audits of prescribing decisions to ensure safe prescribing, and that it would regularly review its services in line with regulatory standard and guidance. None of these mitigations had been implemented. The RA was not dated and there was no information about whether it had been reviewed.

The pharmacy worked with one prescriber. The prescriber was a medical doctor who routinely worked at an adjoining, independent hair-loss clinic. The clinic was registered with, and regulated by, the Care Quality Commission (CQC). The pharmacy did not ask their prescriber to provide evidence of their training or competence to prescribe medicines for hair loss. The SI explained they relied on the prescriber's position at their clinic as proof that they were competent to prescribe these medicines. The pharmacy did not request information from the prescriber about their professional indemnity insurance arrangements.

The pharmacy had documented policies in place to help manage the safe prescribing and supply of most of its medicines. The policies provided some details to help manage the safe prescribing of each medicine. These included the signs and symptoms of the presenting condition, information to aid a differential diagnosis, and inclusion and exclusion criteria for receiving the medicine. The policies provided red flag information, details of dosage and duration, and contraindications. And provided details of the necessary records to support prescribing, and the references used to help create the prescribing policies. The SI explained how they had provided a copy of these policies to the prescriber. And that they expected the prescriber to work within the scope of the policies. But the pharmacy did not have any evidence that the prescriber had read the policies, or whether they had agreed to work within the policies' boundaries. The SI admitted that they had taken it on goodwill that the prescriber would use the policies as intended.

The pharmacy did not have any systems to regularly audit prescribing to determine whether the prescriber was using the pharmacy's policies to inform their decisions. And it did not consider any requirements for ongoing monitoring to establish if repeated supplies were safe and appropriate. Or to highlight areas that were appropriate for the pharmacist's intervention. The pharmacy's owners had completed an ad hoc audit in 2023, which considered various aspects of the pharmacy's service. Some findings from the audit were briefly documented. But there was no information about outcomes based on the audit's findings. Or any changes that had been made in response to improve the pharmacy's services. One example of a finding following scrutiny of completed consultation forms was that consultation forms were sometimes incomplete. And that the patient and the customer placing the order were not always the same person. There was no evidence that any changes had been made to address these issues. And the SI admitted that no changes had been made since the audit had been completed.

The pharmacy did not have a process to seek consent from people to share information about the services provided to their usual NHS prescriber. The SI explained how they presumed the service's prescriber would discuss this with people and share any necessary information. But they were not aware of any policies guiding the prescriber about consent. Or to help the prescriber determine how to proceed if people refused to grant consent to share information with their usual prescribers. The SI explained they would only consider sharing information with someone's regular prescriber if there was an issue with their request or the information they provided. And there was no evidence of them ever having done so.

All the medicines the pharmacy provided were unlicensed medicines manufactured by a licensed specials manufacturer on the pharmacy's behalf. The pharmacy did not have any policies or SOPs to help manage the safe supply of unlicensed medicines to people. The pharmacy did not tell people on their website that their medicines were unlicensed. And there were no process in place to inform people about this and to help them manage the risks when they received these medicines. Despite not advertising treatment for women on the pharmacy's website, the pharmacy regularly treated women as part of their service. The pharmacy did not have any risk assessments in place to manage the risks of treating different genders with the same medicines, especially to manage the risks of providing unlicensed products containing finasteride and dutasteride to women. The pharmacy's prescribing policies listed women in the exclusion criteria for all the medicines it provided, with a statement that "off-label use required specialist referral". The SI was asked to explain what this meant, given that all the medicines being provided by the pharmacy were unlicensed, or "off-label". The SI explained it was down to the prescriber's discretion whether to prescribe the medicines to someone who was female. If the prescriber chose to prescribe for someone who was female, the pharmacy contacted the person and asked them to read and sign a consent form. The SI provided some examples of completed consent forms. The forms provided people with information about some scientific evidence to support the use of minoxidil and finasteride in women, the risks of using the medicines including risks of teratogenicity during pregnancy and the risks during breastfeeding, potential side-effects, and instructions for use. The consent form did not provide any information about the risks associated with the unlicensed nature of the medicines.

The pharmacy did not have any access to notes made by the prescriber during their consultation process. There was no information available about whether the prescriber had conducted a verbal or face-to-face consultation with people. Or whether they had simply relied upon the information people provided in their online questionnaire. Pharmacy team members were able to see the information people provided in response to the online questions. But they admitted they did not routinely check this information. There was no documented procedure to help them make necessary and effective checks of the information people provided. They were satisfied that the prescriber had completed all necessary diligence to ensure safe prescribing if they provided a prescription to the pharmacy to dispense. There was no evidence of the pharmacist making interventions or having conversations with people about the medicines they were prescribed. The pharmacy had access to a spreadsheet that the prescriber completed. The spreadsheet provided names of people who had received a prescription and those whose request had been refused. But the pharmacy had no access to any information the prescriber had used to justify these decisions. The SI admitted that pharmacy team members did not usually access the spreadsheet. Instead, they waited for a prescription to arrive, which they then dispensed.

Pharmacy team members highlighted and recorded mistakes identified before people received their medicines, known as near misses. But there were no 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 improving the labelling of containers where stock was stored to help prevent errors selecting the wrong product. But, team members rarely recorded specific information about why the mistakes had been made. Or the changes they had made to prevent a recurrence and to help aid future reflection and learning. And they did not regularly analyse the data to establish patterns of mistakes. So, they may miss opportunities to learn and make improvements. The pharmacy recorded dispensing errors, which were errors identified after the person had received their medicines. People used a form on the website to contact the pharmacy. There was no documented procedure to help team members manage errors effectively. The SI explained how they would manage a dispensing error. But there were no records of errors available. The SI explained this was because, to his knowledge, the pharmacy had not made a dispensing error since opening in 2019.

The pharmacy had a documented complaints procedure. But the procedure did not reflect the pharmacy's operating model. It published contact information on its website, but on testing, the telephone number advertised did not work. The pharmacy's website had a contact form people could use to contact the pharmacy. And these forms were handled by the company's customer service representative first, before being passed to the pharmacy. The SI gave an example of a complaint they had received where a person had raised issues with side effects they were experiencing. They explained how they had responded to the person's concerns and how they had resolved the issues. But they had not documented any of the information for future reference.

The pharmacy had current professional indemnity insurance in place. It maintained a complete responsible pharmacist (RP) record. And the pharmacist displayed their RP notice. The pharmacy kept electronic records of the private prescriptions it dispensed. And the sample of these records seen were complete. 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.

The pharmacy had a documented procedure and information available to help pharmacy team members deal with a safeguarding concern. And this provided team members with general information and guidance about how to deal with a safeguarding concern. But the contents of the procedure were not always relevant to the pharmacy's private online operating model. Pharmacy team members had not completed formal safeguarding training. But they gave some examples of how they would appropriately respond to a safeguarding concern. The pharmacy did not have any dedicated procedures or training in place to help pharmacy team members identify and manage potential misuse of the medicines it provided.

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. 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 and a trainee dispenser. The trainee was enrolled on the necessary qualification training to provide dispensing services to people. The pharmacy also employed two other dispensers who were appropriately qualified. Team members completed ongoing learning ad hoc by reading various materials and discussing topics with the pharmacist. The SI explained they had undertaken learning to develop their knowledge of hair loss by reading primary literature sources and academic studies. And by working closely with professionals in the adjoining hair-loss clinic. They had also enrolled on an aesthetics training course because they understood there to be significant crossover in the learning for these two therapeutic areas.

Pharmacy team members explained they would raise professional concerns with the SI or the pharmacy's owners. 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 recently raised concerns with the owners about the way their bespoke products were packaged. In response, the pharmacy's owners had invested in different packaging which had helped to reduce the time taken to dispense the medicines. 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. The SI explained how they felt confident to challenge the appropriateness of prescribing decisions directly with the prescriber. But they did not have any documented evidence of doing this.

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

Summary findings

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

Inspector's evidence

The pharmacy's website, www.densehairexperts.com, 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, and some limited information about the pharmacy's prescriber. But the information provided about the prescriber was not sufficient for people to seek details about the prescriber's registration. And it did not make it clear that the prescriber was a third-party provider who was not employed by the pharmacy. The website provided some information about the conditions treated, but the focus of the information was on the products and medicines the pharmacy provided. And the pharmacy provided comprehensive information to people about the medicines and treatment plans available.

People were required to add their chosen medicine or treatment plan to the cart and complete a financial transaction before they were invited to complete a consultation. And this was by use of wording such as "add to cart", "subscribe" and "one-time purchase". The website's contents, including its home page, promoted the sale of unlicensed prescriptions only medicines (POMs) to the public, and included references to named POMs, including price information. This made the pharmacy's website appear transactional and not condition or consultation driven. 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. This was not in accordance with GPhC and MHRA standards and guidance and meant that people may not always receive the most suitable medicines to treat their condition.

All of the medicines offered by the pharmacy were unlicensed topical medicines 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 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 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.

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

Summary findings

The pharmacy does not have adequate safeguards to ensure people receive medicines which are suitable for them. And pharmacy team members do not keep or have easy access to records to make effective clinical assessments. The pharmacy's dispensing labels are missing key information and are not legally valid. And the pharmacy does not label all stock containers appropriately. The pharmacy's services are generally accessible to people. And team members make adequate checks of medicines to make sure they are in date and suitable to supply.

Inspector's evidence

People did not visit the pharmacy. They communicated with the pharmacy primarily by using the contact us form on the pharmacy's website. Or by telephone, although this was not working at the time of the inspection. The pharmacy's website provided contact details and some 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.

The private prescriptions dispensed by the pharmacy were generated electronically using the pharmacy's website. If the prescriber chose to prescribe for a person, they printed and signed each prescription using a wet signature. Prescriptions were then passed to the pharmacy to dispense. The prescriptions seen were complete and contained all the legally required information. The prescriber was a third-party contractor. And the SI gave assurances that the prescriber kept records of their consultations with people. But the pharmacy did not have access to these records, or any other clinical information the prescriber had used to inform their decision making. The pharmacist's clinical checks appeared basic made with little information outside of what was on the prescription. They didn't make checks against their prescribing policies or check the person's completed questionnaire. There were no pharmacy policies to help the pharmacist determine the appropriateness of quantities to supply and how frequently supplies should be made. This meant it was difficult to make an effective clinical assessment of prescriptions being dispensed. The SI explained they did not record any interventions they made when dispensing these prescriptions. And team members did not routinely tell people that the medicines they were receiving were unlicensed. Or provide them with information about how to understand and manage the risks of using an unlicensed medicine.

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 stock containers, which team members then used to decant smaller quantities into the pharmacy's packaging. Team members wore protective gloves when decanting these liquids. And they used a specific bench in the pharmacy to carry out their liquid measuring and decanting. The name, batch number and expiry date of each medicine was applied to the pharmacy bottles after being prepared. Team members printed this information onto the bottles. Then they placed the filled bottles on the pharmacy's shelves ready to be assembled and dispensed against a prescription. During the inspection, several prepared bottles were found with blurred or missing printing. The SI explained that the current system they used to print necessary information onto bottles did not work if there were residues of medicine on the bottle. This meant that the pharmacy couldn't be sure that these stock bottles always had the required details on so action could be taken after a reported adverse reaction or batch recall.

When a prescription was received, pharmacy team members selected the relevant product and attached a dispensing label to each container. But the labels did not contain the address of the pharmacy. This meant the labels did not comply with current legal requirements and made it difficult for people to know where the medicine was dispensed. Pharmacy team members signed the 'dispensed by' and 'checked by' boxes on dispensing labels during dispensing. 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 SI sometimes worked alone in the pharmacy, and this required them to check their own dispensing work. The SI acknowledged the risks of checking their own work and explained how they managed these risks by taking a break in the process to help separate the dispensing and checking parts of the process.

The pharmacy packaged medicines in a branded bag, which was sealed with a label showing the person's details and the content of the bag. The label also contained a QR code, which people could scan to access a patient information leaflet about their medicines. These bags were then placed in another bag provided by the courier, which was sealed and had a shipping label attached, with the person's name and address. 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 SI explained their understanding about how the courier returned the package to the pharmacy for the team to investigate. But they were unclear about whether the courier attempted to redeliver a package, where medicines were stored while waiting to be redelivered, and how long the courier held a package before returning it to the pharmacy. 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. The nature of the medicines they dispensed meant that all medicines had a maximum of three months expiry. And medicines with less than three months were rotated so they could be used for someone's monthly treatment, before being segregated and destroyed if they had less than a month's expiry left. After a search of the shelves, no out-of-date medicines were found.

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 several plastic measuring cylinders available, which team members used to measure stock medicines into the pharmacy dispensing bottles. The measures were clean and each medicines had its own marked cylinder to help prevent cross-contamination. The pharmacy had the necessary equipment to restrict access to the premises. Pharmacy team members had resources available including the British National Formulary (BNF) and use of the internet. The pharmacy had a shredder available to destroy its confidential waste. It kept its computer terminals in the secure pharmacy, and these were password 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.