General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Hairology Pharmacy, The Studio, 72 West Street, Marlow, SL7 2BP

Pharmacy reference: 9011955

Type of pharmacy: Aesthetic services clinic or beauty salon

Date of inspection: 12/06/2024

Pharmacy context

This is a private pharmacy in the centre of Marlow, Buckinghamshire. The pharmacy has its own clinic and prescribing service which is provided by a pharmacist independent prescriber. It subsequently only dispenses private prescriptions and provides private services. This includes specialising in and supplying specific treatments for hair loss. The pharmacy also manufactures and supplies unlicensed topical hair loss products through the prescribing service. The pharmacy does not provide any surgical treatments, but it can offer collagen induction therapy (microneedling). And it has its own website (https://hairologycentre.com/).

Overall inspection outcome

✔ **Standards met**

Required Action: None

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Summary of notable practice for each principle

Principle	Principle finding	Exception standard reference	Notable practice	Why
1. Governance	Standards met	N/A	N/A	N/A
2. Staff	Standards met	2.2	Good practice	The pharmacist has ensured that he is suitably qualified and has the necessary skills to deliver the pharmacy's services.
		2.4	Good practice	The pharmacist routinely ensures his knowledge is kept current in his field of practice. He continues to specialise in trichology and actively participates in relevant and accredited training to help underpin his knowledge.
3. Premises	Standards met	N/A	N/A	N/A
4. Services, including medicines management	Standards met	N/A	N/A	N/A
5. Equipment and facilities	Standards met	N/A	N/A	N/A

Principle 1 - Governance ✔ Standards met

Summary findings

The pharmacy has organised and efficient processes in place. The pharmacy's business model involves prescribing, preparing, and mainly supplying unlicensed medicines. This has additional associated risks, but the pharmacy identifies and appropriately manages them. It has written procedures to help provide suitable guidance. And the pharmacy routinely shares information about a person's treatment with their usual prescriber. This helps to ensure they are aware of people's prescribed medicine(s) through the pharmacy's services. The pharmacy keeps people's confidential information safe. Members of the pharmacy team understand safeguarding requirements. And the pharmacy's records are comprehensive. But the team could do more to independently verify the identity of people who use their services.

Inspector's evidence

This is a new pharmacy. The pharmacy supplied mainly unlicensed topical treatments which were manufactured at the pharmacy under section 10 of the Medicines Act 1968. This meant the medicines did not hold a UK marketing authorisation and were unlicensed (see Principle 4). They were prescribed after an extensive consultation with the superintendent pharmacist (SI) who was also a pharmacist independent prescriber (PIP) and the responsible pharmacist (RP). The correct notice to identify the pharmacist responsible for the pharmacy's activities was on display.

The pharmacy had an appropriate range of documented standard operating procedures (SOPs) in place to provide guidance about the services it provided. They were specific to the nature of the pharmacy's business. Relevant risk assessments and audits had also been completed to verify the safety and quality of the service being provided. There was, therefore, effective oversight in place to oversee the safe supply of medicines. The SI was aware of national guidelines and prescribing for licensed medicines was in line with these. The pharmacy also had prescribing guidelines for prescribers in place which helped practise safe prescribing. Consultation notes made by the prescriber were comprehensive and included all necessary and relevant details. Any discussions that took place between the person receiving the pharmacy's services and the prescriber were also routinely documented.

The pharmacy advertised its services online, through its own website. People who used the pharmacy's services were sent emails asking for feedback. The RP said that he had not received any feedback from other healthcare professionals such as from people's usual prescribers. The pharmacy had a complaints and incident handling process in place. The RP confirmed that there had been no dispensing incidents, formal complaints or prescribing errors since the pharmacy had opened. The pharmacy supplied medicines against each private prescription that was issued on a one-to-one basis. So, for each person using the pharmacy's services, ample time was scheduled for the consultation, after which the prescription was issued, medicine(s) were then prepared, dispensed, and supplied. This helped reduce the risk of a selection error occurring. Relevant details were checked against prescriptions during the dispensing process. People were counselled during the consultation and relevant written information provided. The pharmacy was exceptionally clean and tidy. The SI confirmed that there had been no near miss mistakes made. However, there were no details recorded about this which was advised accordingly.

The pharmacy ensured people's confidential information was kept secure. This included securely

storing clinical records. Confidential waste was suitably disposed of, and the pharmacy used a secure system to ensure people's details were retained appropriately. The pharmacy's computer systems were password protected, encrypted and backed-up appropriately.

The RP had trained to level two to safeguard the welfare of vulnerable people and the pharmacy had contact details available for relevant safeguarding agencies. Consultation records made by the SI were seen to be clear and accurate. They clearly documented whether a chaperone was required, and the pharmacy had a chaperone policy. Medicines were prescribed and supplied to people between the age of 16 to 80. The SI explained that genetic hair loss in teenagers was rare and there were more risks involved in prescribing for people over the age of eighty due to co-morbidity and polypharmacy. People who were pregnant or breastfeeding were excluded from the service. The RP also counselled people to stop using the products if they became pregnant. Verbal consent was obtained to share details with people's usual GP or prescriber, relevant details were also documented, and this information was sent or provided to people to supply to their prescriber. No remote consultations took place, but limited checks were made to verify people's identity. This was discussed at the time.

The pharmacy had suitable professional indemnity insurance arrangements in place. The SI confirmed that it covered the activities carried out at the pharmacy. The pharmacy did not hold and had not supplied any controlled drugs (CDs), medicines which required refrigeration or emergency supplies. The RP record and records to verify supplies made against private prescriptions had been maintained in accordance with legal requirements. There were also records to verify the pharmacy's activities relating to the extemporaneous preparation and supply of unlicensed medicines as well as certificates of conformity from wholesalers, where applicable. However, at the point of inspection, the relevant information, which was required by law was maintained in three separate places or on three different records and required cross-referencing. Incorporating this information into one sole record was discussed at the time and agreed by the SI to implement.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough staff to manage the pharmacy's services safely and effectively. The prescriber is suitably qualified and experienced to prescribe in his respective role. And he ensures his knowledge is kept current by completing relevant ongoing training.

Inspector's evidence

The pharmacy had enough staff in line with the pharmacy's current volume of work. Contingency arrangements involved locum staff covering who only dealt with dispensing or queries. Consultations and prescribing only occurred if the RP was present. The RP was a qualified PIP, and he was prescribing medicines that were within his area of competence. He had specialised in the field of trichology and his previous employment provided relevant experience. He held membership with various trichology societies (such as a trichologist's society in Italy and the World Trichologist Society). He was a member of the Primary Care Dermatology Society UK and a member of the Society of Cosmetic Scientists. In addition, the RP was currently undertaking an evidence-based hair loss fellowship with one of the world's most comprehensive training programmes in hair loss (Donovan Hair Academy). He explained that this was an 87-week course with three hours of lectures, weekly assignments, case studies and discussions. Peer reviews also took place with a clinical pharmacist. The RP had completed relevant accredited training to offer collagen induction therapy, but this service had not been provided at the point of inspection. Certificates to verify completion of ongoing training were seen. Services were paid for privately by people using the pharmacy's services. There was no financial incentive for a prescriber to provide a prescription. The RP said that prescriptions being issued were dependent on the person's condition and clinical diagnosis.

Principle 3 - Premises ✔ Standards met

Summary findings

The pharmacy premises provide a suitable environment to deliver healthcare services from. The pharmacy is professional in appearance, kept clean and tidy. And it has enough space to provide its services.

Inspector's evidence

The pharmacy was situated in the town centre. The pharmacy premises consisted of a small reception area made up of clear open space, the dispensary was behind this, two consultation rooms and staff areas were at the very rear. The pharmacy's premises were very professional in appearance and clean. Staff wiped down surfaces and used additional measures to ensure equipment was clean (see Principle 5) after each use. The premises were also cleaned regularly. This assisted in providing a suitable environment for the services provided. The ambient temperature inside the premises was suitable for the storage of medicines and the pharmacy was bright and well ventilated.

The pharmacy had enough workspace for its current level of workload. This included dispensing, manufacturing, storing medicines and for holding or storing any necessary equipment. Manufacturing or preparing unlicensed medicines took place on one side of the dispensary. Medicines that had been pre-prepared were also stored here in an ordered way. There was a hatch in the dispensary which opened on one side of the reception and waiting area, appropriate seating was provided here, and this enabled people to speak directly to the RP if needed. The pharmacy was also appropriately secured against unauthorised access.

The pharmacy had its own online website (https://hairologycentre.com/) where its services were advertised. This website gave clear information. It displayed information about the pharmacy's opening times, the pharmacy's contact details, some details about the products and services available but there was no specific information about the SI or details about the pharmacy's complaints procedure. The pharmacy did not provide any services at a distance or remotely.

One of the consultation rooms was used by the RP, the other was rented to another company who provided various aesthetics treatments. The consultation rooms were of a suitable size for their intended purpose. The RP explained that the company who provided aesthetics treatments was a nurse-led service who provided various treatments on an appointment basis, on a few days in the week. As this service was not taking place on the registered pharmacy blueprint, this service is outside the jurisdiction of the GPhC.

Principle 4 - Services ✔ Standards met

Summary findings

Overall, the pharmacy has safe working practices. The pharmacy maintains suitable records to show that appropriate checks are undertaken about the medicines it prescribes and supplies. And the pharmacy follows up to monitor people who receive treatment. The pharmacy's services are easily accessible to people. The pharmacy sources its medicines from reputable suppliers. It stores and generally manages its medicines correctly. But the pharmacy doesn't always follow all the guidance set by the GPhC when it prepares unlicensed medicines. This limits its ability to show that it provides this service appropriately.

Inspector's evidence

The pharmacy was open Monday to Friday 9am to 5.30pm and opening hours were listed on the front of the premises. The RP signposted people to relevant services (such as a dermatology clinic in a nearby town) from his own knowledge and links through his practice. People with restricted mobility or using wheelchairs could easily access the pharmacy's services and consultation room from the design and layout of the premises. The pharmacy could print dispensing labels with a larger sized font for people who were visually impaired. Translators, representatives, or Google translate were used for people whose first language was not English and when an appointment was booked, any information about adjustments was provided at the time which enabled the RP to prepare accordingly.

The pharmacy's website offered an option for a remote or video consultation. However, the RP explained that the pharmacy's policy was that the initial consultation had to be face-to-face. He asked people to come in if they selected this option as he needed to visually see people's scalps to diagnose their condition. Consultations were therefore in-person and no remote consultations had taken place.

The pharmacy predominantly supplied different strengths of unlicensed topical minoxidil and finasteride tablets to people in the UK. The RP followed national prescribing and UK guidelines where applicable (such as from the Primary Care Dermatology Society). The prescribing service involved people making an appointment with the RP, he initially created their profile which had relevant personal details and at the outset of the consultation, the RP explained the process, took a full medical history, asked about and assessed whether a chaperone was needed, examined people's scalps after obtaining their consent to do this and took photographs of this area. The RP explained that he always ensured that people took part in the decision-making process. Verbal consent was obtained to share details with people's GP, and this was documented in the clinical notes. At the end of the consultation, the person was given time to read the consultation notes, after which they signed and dated this. This helped reinforce their awareness of all the details. Consultations took one hour.

If suitable and applicable for treatment, the RP subsequently prescribed and usually supplied one month's treatment. A follow-up occurred after the first two weeks of initiation where the RP checked side effects and whether any adverse reactions had occurred, people were then counselled accordingly. They could also contact the RP via telephone or email if they had any questions, issues, or queries. People's progress was then monitored, reviewed and details documented after three, six and then nine months.

The RP routinely safety-netted during his consultations. He explained to people about the symptoms

they needed to watch out for, adverse reactions were routinely checked, and advice provided, for example about palpitations. People's blood pressure (BP) was not checked during the consultations. The RP explained that the onus was on the person to have their BP checked. As minoxidil was for topical use, reduced absorption took place (1-2% was described) hence the risk was deemed to be lower. Only a few people received medicines prescribed by the RP which could have been affected by this, and there had been no issues such as palpitations or changes in blood pressure. Relevant details were routinely documented, and full records of consultations made to help verify this. However, people's medical histories were not independently verified through any other mechanism and the pharmacy was dependent on people providing accurate information. There had been no requirement to signpost, refer or escalate and no inappropriate requests, nor multiple orders. There had also been no asynchronous prescribing and no refusals; the RP had noticed that people generally underused the treatment supplied because of the expense involved as they tried to make their treatment last longer. The RP had seen, made and recorded details of interventions and examples were provided.

The pharmacy used a courier service (Royal Mail) that had tracking facilities to deliver ongoing supplies. A signature was required upon receipt, no CDs or temperature sensitive medicines had been supplied and no failed deliveries.

After the consultation, the process moved to the dispensary whilst people waited outside in a designated area. Patient medication records (PMR) were created, and the relevant details processed. After the staff had generated the dispensing labels, there was a facility on them which helped identify who had been involved in the dispensing process. Team members routinely used these as an audit trail. People were counselled on how to use the medicine(s) during the consultation but also after dispensing and relevant patient information leaflets (PILs) were printed and provided.

The pharmacy extemporaneously prepared different formulations of minoxidil for people against prescriptions issued by the RP. The formulations were prepared on one side of the dispensary. This area was kept clean and tidy. Hazardous materials were kept inside a safe, designated and purpose built for flammables. The pharmacy held a Customs and Excise license which enabled it to order these materials. Other excipients were also stored suitably. The excipients or raw materials had certificates of conformity or analysis available.

Topical medicines containing minoxidil had been pre-prepared and were clearly labelled with all the relevant details, this included batch numbers and expiry dates. The RP explained that a six-month expiry date was applied to these preparations. The pharmacy had processes in place to show how these formulations were prepared. Records made, had the calculated amounts of the excipients to be used. A formula from an approved source was used which made it possible to determine or verify the calculated quantities. Records of the batches that had been prepared had been maintained but there was no independent source or external assessor used to validate the formula and verify the calculations. The RP explained that he was currently looking into options about this but there were excessive costs involved.

The pharmacy's stock was stored in a very organised way. Licensed wholesalers were used to obtain medicines, medical devices and relevant excipients or alcohols. Medicines were date-checked for expiry regularly and short-dated medicines were routinely identified. There were no date-expired medicines or mixed batches seen but appropriate records had not been kept verifying when this had taken place. This made it difficult for the pharmacy to show that this process had been routinely occurring, but records of destruction had been maintained. Medicines returned for disposal, could be accepted by staff or collection arranged, and stored within designated containers. Drug alerts were received electronically and actioned appropriately. Records were kept verifying this.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the relevant equipment it needs to provide its services safely and effectively. The equipment is new and maintained appropriately. The pharmacy's equipment and surfaces are kept clean. And some equipment helps provide the required level of technical expertise. This assists in providing additional assurance to people using the pharmacy's services.

Inspector's evidence

The pharmacy had a range of equipment to help manufacture unlicensed medicines. The equipment was new or had been calibrated and was kept exceptionally clean. This included weighing scales, a water bath, a hopper (to formulate creams if required) and a PH meter. The latter helped ensure the PH range for unlicensed topical medicines was within the required range. Equipment to assist with mixing included different sized beakers, funnels, spatulas, pipettes, and droppers. In keeping with the services provided, the pharmacy did not have a pharmaceutical fridge or CD cabinet as they were not required. The dispensary sink for reconstituting medicines was clean. The pharmacy had hot and cold running water available. Computer terminals were positioned in a location that prevented unauthorised access and the team had access to relevant reference sources if required. All surfaces within the dispensary were cleaned with industrial methylated spirit (IMS) before preparing or manufacturing medicines and the RP used personal protective equipment when manufacturing. This included gloves and face masks for protection and to prevent contamination occurring.

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.