

Registered pharmacy inspection report

Pharmacy Name: The Belgravia Pharmacy, 9 Longmoore Street,
London, SW1V 1JH

Pharmacy reference: 9010998

Type of pharmacy: Community

Date of inspection: 16/06/2022

Pharmacy context

The pharmacy is situated in central London close to Victoria station. It is part of a private clinic which specialises in treating hair loss. The pharmacy manufactures and supplies bespoke topical hair loss medications for clients of the clinic. The clinic has a website www.belgraviacentre.com and it offers both face-to-face and remote consultations. It does not offer any surgical treatments and it is not registered with the Care Quality Commission. The clinic's prescribers are all pharmacists.

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	N/A	N/A	N/A
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 prepares and supplies unlicensed medicines which carries some additional risks, but it generally identifies and manages these to make sure its services are safe. And it keeps clear and accurate records. The pharmacy team members are clear about their roles and responsibilities, and they follow procedures, so they work effectively. They understand their role in protecting vulnerable people, and they keep people's private information safe.

Inspector's evidence

The pharmacy and the clinic were part of the same legal entity. The superintendent pharmacist managed the pharmacy team and worked as one of the regular responsible pharmacists (RPs). The RP on duty displayed a notice with their GPhC registration details so people could identify them. The pharmacy had standard operating procedures (SOPs) which the superintendent had written, and they were periodically reviewed. The SOPs were tailored specifically to the pharmacy's unique activities, so they provided clear work instructions for the team. The team members signed a training record to show they had read and understood them, and they worked under the supervision of the RP.

Pharmacist independent prescribers (PIPs) working in the pharmacy prescribed hair loss medication after the person had undergone a detailed face to face or remote consultations with one of the clinic's trained hair care specialists. Most of the medicines prescribed were unlicensed topical hair loss treatments which the pharmacy extemporaneously prepared under section 10 exemption of the Medicines Act and then dispensed. The PIPs were not usually involved in the consultation, and they prescribed based on the recommendation of the hair loss specialist, so they were effectively acting as supplementary prescribers.

Treatments contained different combinations and strengths of ingredients. Minoxidil was the main active ingredient, and this was combined with other ingredients such as medroxyprogesterone, azelaic acid, caffeine and bio complex, which contained vitamins. The superintendent explained that the unlicensed hair loss medications were developed based on research papers, experience, and feedback from clients. After some research and following discussions between the superintendent, trichologist and two pharmacist who assisted with product development, the pharmacy had introduced some new products containing finasteride in the last year. The team also discussed any new products with the dermatologist who advised the clinic. The pharmacy usually trialed new products on male clinic staff in the first instance to check for any adverse reactions.

The superintendent dealt with any complaints concerning medications and she usually resolved these informally by speaking to the person raising the issue. There was information about the clinic's approach to handling complaints on the website, but it was not easy to find and it did not clearly explain the process. People were able to provide feedback at their follow up reviews and by contacting the clinic. The clinic emailed everybody after their consultation, asking them for feedback on their experience. The team shared and discussed feedback so they could make improvements. All feedback was collated on a spreadsheet so that the team could monitor for common problems or issues that arose regarding treatments or the service and take appropriate action. The superintendent completed audits to monitor the safe running of the pharmacy, but the pharmacy did not complete any clinical audits.

The superintendent used a risk framework to identify potential risks to the team member and people using the pharmacy. For example, the team had considered the risks prior to initiating manufacture of finasteride containing products and set up a separate room with specialist equipment dedicated to this activity because of the risks associated with this medicine. The team recorded medication errors and dispensing incidents and discussed these so they could learn from them.

The superintendent provided confirmation of the pharmacy's professional indemnity insurance. The pharmacy used a recognised patient medication record system to record prescription supplies. Private prescription registers and RP records were integral to this system. The team kept extemporaneous worksheets for each unlicensed medicine that it prepared. Prescriptions were paper based, and the team recorded the batch details of each unlicensed medicine it dispensed and supplied, so these were also a 'specials record'. The clinic had a bespoke electronic clinical record system used to record consultations including the person's medical history, allergy status, any medication that they were taking. The hair care specialists recorded detailed consultation notes which included people's medical history and evidence such as photos and trichoscope images of the hair follicles. And the PIPs had full access to these records so they could review them when prescribing hair loss medications.

All of the clinic's staff signed a confidentiality agreement, and the company was registered with the Information Commissioner's Office. The company's privacy policy was available on the website. The team members stored confidential material securely and they segregated confidential paper waste for safe disposal. Electronic records were password protected and the clinic kept paper patient records including prescription in locked cabinets in the clinic reception area.

The clinic had a minimum age of 16 for treatments but finasteride containing products were only supplied to men over 18. People provided consent and proof of ID during the initial consultation. People who were pregnant or breastfeeding were excluded from any service which required the use of medication. Advice was provided for people of a childbearing age to use protection if using a finasteride containing medication. The pharmacy team members had completed level 2 safeguarding training.

Principle 2 - Staffing ✓ Standards met

Summary findings

The pharmacy has enough staff to manage the workload and delivery the services safely. The pharmacy team members have the right skills and qualifications for their roles, and they work to professional standards. The team works well together in a supportive environment and the pharmacy team members get opportunities to learn and improve.

Inspector's evidence

The pharmacy team included the superintendent pharmacist, a pharmacist manager, two regular locum pharmacists, six pharmacy technicians, four of whom were qualified as accuracy checkers and one trainee technician. The regular pharmacists were qualified as PIPs and the pharmacy staff had completed their training whilst working at the pharmacy.

The wider clinic team included a lead hair care specialist who was a trichologist, and a number of hair care specialists who were all nurses or pharmacists, treatment advisors, clinical therapists and reception or administrative staff. The trichologist was qualified and registered with the Institute of Trichologists. Hair care specialists completed a one-month induction programme with the trichologist under close supervision which included understanding of theory, practical demonstrations and scalp examinations, the use of trichoscopes and decision making. There was a comprehensive training manual which trainees had to read during their induction. Trainees were assessed by the trichologist before they were allowed to practice and they were always accompanied initially by a senior specialist. Although there was evidence of communication between the trichologists and the trainees, they did not have a formal training portfolio. The superintendent trained the PIPs working in the pharmacy and completed a modified version of this induction, so they understood the overall process.

Treatment advisors provided clients with ongoing support and advice and clinical therapists offered hands on treatments on the recommendation of the hair care specialist. Advisors and therapists were not involved in the pharmacy service or consultation process.

Clinical notes were regularly reviewed by the trichologist to ensure the hair loss specialists followed the protocols. The team had access to a dermatologist who acted as an external advisor so they could seek advice on scalp presentations which required more specialised expertise. The clinic ran occasional training sessions to discuss interesting or complex cases, new formulations and feedback from clients, and the pharmacy team members could attend these.

The pharmacy team members communicated openly and worked well as a team. There was no formal appraisal process but team members could provide feedback and raise issues with the superintendent if needed. The clinic had a whistleblowing policy. The superintendent pharmacist reported to the two company directors and worked closely with them. This was a private clinic where the company profited directly from providing the service, however there was no incentive scheme or targets set for the pharmacy team members.

Principle 3 - Premises ✓ Standards met

Summary findings

The pharmacy is suitable for the services it provides. It is professional in appearance and well maintained.

Inspector's evidence

The pharmacy relocated to the current premises in 2018. It was a large spacious building arranged over two floors: a ground floor and basement. The pharmacy was situated in a partitioned unit on the ground floor close to the reception area. It consisted of three adjoining rooms; the team used one for manufacturing, another was for packaging the unlicensed medicines and the third was for dispensing prescriptions and administration. There was a hatch to the reception and waiting area so people could approach and speak to the pharmacy team. The pharmacy had enough work and bench space for the activities undertaken.

The team used a fourth room in the basement to manufacture finasteride preparations and this was part of the registered area. The clinic's consultation rooms, treatment pods and offices were situated in the basement and could be accessed via stairs or a lift. Fittings were in good order and the clinic and pharmacy were bright, clean and well organised. Air conditioning controlled the room temperature. The team monitored the room temperature in the rooms used for manufacturing. The pharmacy did not have a dedicated consultation room but the pharmacy reception area was quiet and the team members could use one of the basement consultation rooms if people needed to talk in private

The clinic's website provided detailed information about hair loss and the clinic's service and people could use it to book an appointment. Medicines were not promoted on the website.

Principle 4 - Services ✓ Standards met

Summary findings

The pharmacy's working practices are safe and effective. It has clear processes for preparing and supplying medicines. The pharmacy sources and manages medicines and pharmaceutical ingredients appropriately, and it takes the right action if it identifies defective medicines.

Inspector's evidence

The pharmacy's opening hours were Monday to Thursday 9am-8pm, Friday 9am to 6pm and Saturday 9am to 5pm. The clinic mainly promoted its services via the website and social media. People could make an appointment by telephone or via the website. They could complete an online consultation questionnaire on the website, but this was only a preliminary step prior to a remote video consultation or a face-to-face consultation in the clinic. The trichologist explained that most people's first consultation was face-to-face. The clinic treated both men and women with hair loss and it had some clients from outside of the UK. The hair loss specialists informed people that the clinic's medications and treatments were not licensed during the initial consultation.

Blood pressure was taken for all face-to-face consultations, but bloods were not routinely monitored by the clinic. Hair care specialists checked when clients last had a blood test at their annual medical review, but evidence was not requested to confirm normal renal and liver function which may be relevant for people using minoxidil and finasteride medications. People with known liver or kidney conditions were excluded from using the medications. As the treatment was ongoing, this could mean that changes in liver or kidney function could go undetected especially as these were unlicensed medications, and their safety profile had not been clinically tested. The pharmacy did not notify a person's GP or their usual doctor that they were using an unlicensed medications to treat hair loss, but the clinic advised people to inform their GP. The superintendent explained that they occasionally received queries from a GP when a client had told them they were using treatment and they had sometimes requested that the clinic to stop the treatment. The default of the clinic was to not to initiate or to stop treatment if there were any health concerns that the medication might not be compatible with.

The PIPs were prescribing mainly unlicensed medicines, so outside the scope of national guidelines, and they took responsibility for making sure there was evidence or experience of using the medicine to demonstrate its safety and efficacy. The only licensed medicine that they prescribed was finasteride tablets. The hair loss specialists reviewed new clients after a month and thereafter every three months so the treatment plan could be adjusted if necessary. Treatment was usually ongoing but repeat prescriptions were only issued if people attended their review.

The PIPs used a detailed 'RAG' list containing the clinic formulary to assist them in their decision making when reviewing each client's consultation record before approving and signing the prescription. The PIP who was working as the RP could demonstrate scenarios where he may have a query with the consultation and how he would contact the hair loss specialist who undertook the consultation. If the specialist was not available, he would delay prescribing and inform the client, or he could consult the trichologist if the matter was urgent.

The pharmacy team extemporaneously prepared the unlicensed medications in large batches and

packed these down into 60-70 smaller containers for dispensing purposes. The medications were all topical and included creams and lotions. Ingredients and raw materials used to prepare unlicensed products were mainly sourced via an intermediary UK based company specialising in sourcing pharmaceutical ingredients. Ingredients had certificates of analysis. The pharmacy commissioned a UKAS accredited laboratory to analyse random samples of the unlicensed preparations every 3-4 months of the unlicensed preparations to ensure these were within specification. Propylene glycol was the main vehicle for the lotions, but the pharmacy also used glycerine for people who were allergic and patch tests were sometimes completed for people with sensitive skin. The pharmacy had a Customs and Excise licence to enable them to order alcohols and these were stored in flammable cupboards. The team members received health and safety training which covered actions they should take in event of skin contact or spillages. All of the pharmacy team members were able to undertake all dispensing duties, including the preparation of unlicensed medicines. Finasteride preparations were not prepared by team members of childbearing age due to the risk of birth defects in unborn babies. The pharmacy team members worked in pairs, so each production stage was double checked by a colleague, and an audit trail on the worksheet identified which team members had prepared each batch. The team had manufacturing instructions with ingredient quantities in Perspex holders so they could easily refer to them whilst working. They understood what tasks could not be undertaken if the pharmacist was not present.

The pharmacy applied a seven-month expiry date on all unlicensed medicines which was based on stability testing originally undertaken by an external company. Medications were clearly labelled to show what they contained, and they included batch numbers and expiry dates and were marked 'For External Use Only'. The pharmacy used licensed wholesalers to obtain other licensed medicines. It only stocked one or two licensed medicines for issue against clinic prescriptions. The pharmacy stored medicines appropriately and there were procedures to rotate and date check stock. The pharmacy had an agreement with an authorised waste contractor and the team segregated obsolete and unwanted medicines. It did not stock or supply any CDs or medicines requiring refrigeration.

The pharmacy team members dispensed and labelled prescriptions and these were accuracy checked by the RP. There was an audit trail on dispensing labels which confirmed this. The pharmacy supplied bespoke information leaflets with instructions explaining how to use and store each unlicensed medication. The leaflet also provided information about side effects and contraindications. The pharmacy provided people with 1ml syringes spatulas or spoons so they could control the amount of medication they used. They could access videos which showed how to use the medications and could contact their hair loss specialist if they had any queries. The pharmacy normally supplied 3 months treatment at a time; the maximum amount was 6 months.

People sometimes collected their prescription from the pharmacy themselves, but a large proportion were sent using a Royal Mail tracked service. The team used opaque padded tamper proof packaging to dispatch medications, so the contents were not revealed. Customs declarations were completed when sending medicines to people living overseas.

The pharmacy kept a log for each unlicensed medication showing the date range when the pharmacy supplied a specific numbered batch. This meant they could identify and contact people who had received a supply from a certain batch if it was defective. The team members could only recollect one occasion when this occurred when a client informed them that the medication had crystallised, so they had recalled the whole batch and re-dispensed using a new batch of medication. The pharmacy also received MHRA email medicine and medical device alerts, but they were generally not relevant to the pharmacy.

Principle 5 - Equipment and facilities ✓ Standards met

Summary findings

The pharmacy is well equipped, and it has the right facilities to provides its services safely. The team maintain the equipment, so it is fit for purpose.

Inspector's evidence

The team used glass or plastic containers to package unlicensed medicines. The pharmacy had a range of equipment used for manufacturing including scales, measures, mixing equipment and warming plates. Equipment was clean and of the desired specification. The room used to prepare finasteride preparations had a fume hood to limit the team members' exposure when making these preparations. A service specification record showed it has been last checked in March. Calibration of scales was undertaken regularly. Electrical equipment was in good working order and had a sticker to show it had been recently PAT tested. The PMR screen could not be viewed from the hatch. The team had access to the BNF and to the internet so for reference and research. The team members used personal protective equipment when manufacturing including lab coats gloves, face masks, hair coverings to protect themselves but also to prevent contamination of the medications.

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.