General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Compounding Chemist, HUB-30, Londoneast-UK Business and Technical Park, Yew Tree Avenue, Dagenham, RM10 7FN

Pharmacy reference: 9012121

Type of pharmacy: Internet / distance selling

Date of inspection: 14/11/2024

Pharmacy context

This pharmacy provides its services at a distance, and the premises is not accessible to the public. It is located within a business park and its main business is compounding unlicensed medicines which it prepares in its laboratory. It supplies these and other unlicensed medicines against private prescriptions from external prescribers. The pharmacy mainly supplies dermal creams, gels and solutions, and hair loss tonics. It also supplies medicines against a relatively small number of prescriptions that are generated by its in-house Pharmacist Independent Prescriber (PIP).

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 appropriately identifies and manages the risks associated with its services. The pharmacy team records and regularly reviews any mistakes that happen during the dispensing process so that it can learn from them. It generally keeps the records that are needed by law. And team members know how to protect people's personal information.

Inspector's evidence

The pharmacy had up-to-date standard operating procedures (SOPs). The SOPs covered a range of activities, including responsible pharmacist (RP) duties, and pharmacy and laboratory procedures. The records had been signed by team members to show they had read and understood the SOPs. The pharmacy also had policies, which covered several areas including the premises, staffing and record keeping.

Pharmacy team members recorded dispensing mistakes that happened before a medicine was supplied (near misses). The superintendent pharmacist (SI) carried out reviews of the near misses with the team every four months to help identify patterns and areas for improvement and took action when appropriate to help prevent mistakes being repeated. For example, the same medicine of different strengths were separated on the shelf to avoid picking errors. The pharmacy had processes to learn from dispensing mistakes where the medicine was handed to a person (dispensing errors). Dispensing errors were discussed with the team to generate ideas and make improvements. Although the SI stated they would complete an incident report form for the errors, these were not yet completed for recent incidents that occurred.

The pharmacy had current professional indemnity insurance. The SI explained that the prescribing service was covered by the PIP's professional indemnity insurance. The correct RP notice was displayed. Records required for the safe provision of services were generally completed in line with requirements. Samples of the RP record were seen to be well maintained. The private prescription register was maintained electronically but the date of dispensing and date of prescription were recorded as the same date which could make it harder to find information if there was a query. Records of unlicensed medicines prepared by the pharmacy included most of the required information but did not include any information about the source of the formula or how it had been assessed as appropriate, although most of the master formulas were obtained from one main third party provider. And the records did not include details about the containers used for the ingredients. The SI said that they would update the records and agreed that in future this information would be included. The pharmacy had completed a thorough risk assessment for the service, which covered distance selling, preparing extemporaneous products, remote prescribing, and the individual products that were used during the compounding process. These were dated March 2023 but did not indicate when they would be next reviewed. Following the inspection, the SI provided a risk assessment for the use of a single master formula in compounding products with varying strength of active ingredients. This covered risk of the compounder misinterpreting the document, the risk of inconsistency in the product, compatibility of the ingredients, and process feasibility. The risk assessment outlined the likelihood and severity of the risks along with the controls in place to mitigate the risks. Records of unlicensed medicine supplies were kept electronically and were well maintained. The pharmacy had completed an audit for pharmacy procedures and actions required following the audit were documented. COSHH forms for the

substances handled by the pharmacy team were also available. And there was a locum pharmacist handbook which outlined expectations, quality checks, labelling, and how to package medicines for delivery.

The PIP prescribed topical hair loss treatment based on a set criterion, which included a self-assessment questionnaire, results from a genomic test provided by the pharmacy and for some people a face-to-face assessment carried out by a third-party trichologist. The samples from the genomic tests were analysed by a third-party pharmaceutical company who recommended treatment. The pharmacy had a prescribing policy that was in draft format. Following the inspection, the SI provided a prescribing protocol, which outlined the service access pathway, service inclusions, medicines provided, safety profiles of the medicines, the service criteria (objective, inclusions, exclusions, follow-up, and monitoring) and patient education. The protocol also listed a range of reference sources and research papers. Following the inspection, the SI also provided a sample of prescriptions issued by the PIP. This included three prescriptions that were issued over the last month, with the corresponding consultation forms. The consultation form was a questionnaire-based form and included details about the patient medical history, symptoms, current medication, allergy status and observations. One of the prescriptions sent by the SI also included results from a genomic test carried out, which covered recommendation of the most suitable drugs and supplements, formulas for personalized treatment, including directions on how to use, and complete data that outlines information from medical questionnaire and the pharmacogenetic results.

People were able to give feedback or raise concerns via several means including email, telephone, or by completing an online 'contact us' form on the pharmacy's website. The pharmacy had a complaints log, but this was seen to be empty. The SI reported that the pharmacy had not received any complaints directly from people but had received some feedback via the clinic. Emails from the clinic of issues raised by people to the clinic were available. An example seen was of a complaint raised about the packaging of a medicine. The SI described how they made improvements which resolved the issue. The SI said these would be recorded, with actions taken, in the complaints log moving forward.

All team members and locum pharmacists had signed a confidentiality declaration. There was also a confidentiality policy. Individual logins and passwords were used to access the pharmacy's electronic system. The premises were not accessible to members of the public which helped in protecting confidential information. Confidential waste was shredded on site. A portable telephone enabled the team to ensure conversations were kept private where necessary.

The RP had completed level two safeguarding training. The prescribing pharmacist was the designated safeguarding lead and had completed level three safeguarding training. Team members said they would raise concerns to the safeguarding lead and the pharmacy had a safeguarding policy.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough trained team members to manage its workload. And team members do some ongoing training in the pharmacy to keep their knowledge and skills up to date. Team members feel comfortable about raising any concerns they have.

Inspector's evidence

At the time of the inspection, the team comprised of the SI, the RP, and a trained dispenser, who was also a compounder. The SI worked part time and was available remotely when not on site if the team required support. Team members said there was sufficient staff cover for the services provided. The SI said that if workload increased, it would be completed the following day and she would cover any staff absences.

The SI had completed training in pharmaceutical compounding in the United States and had previously worked in compounding organisations. She was also in the process of completing a master's degree in cosmetic science and completed additional training with an external pharmaceutical compounding company who provided the master formulas. The RP had access to information and training resources provided by this pharmaceutical company and was in the process of completing in house training for compounding. The dispenser had also completed in-house training. And the SI assisted when new formulations were compounded in the pharmacy. The SI was in the process of developing a more structured induction training program. Team members kept their knowledge and skills up to date by reading any new information and reading material the SI shared with them. The PIP's scope of practice was in the management of diabetes and had built experience working in GP surgeries and by providing remote services for other organisations. The PIP completed training in hair loss treatment with another organisation and read the information and reading material shared by the SI to keep up to date.

Informal appraisals were carried out annually with the dispenser to discuss areas of improvement and opportunities for progression. The dispenser aimed to enrol onto the pharmacy technician training course. There were no targets set for the team. The pharmacy had a small team, so team members did not have formal meetings, but they discussed issues, updates, and feedback regularly. The team communicated face-to-face in the pharmacy and via a shared electronic messaging group. The RP could recall a recent update that was shared with the team about the introduction of a new finasteride card. Team members said they worked in an open environment and were able to raise concerns to the SI. Examples of suggestions raised included improvements in packaging, so products were not damaged in transit and other suggestions raised to improve workflow and increase efficiency.

Principle 3 - Premises ✔ Standards met

Summary findings

The premises are clean, and they are secured from unauthorised access. They provide a suitable space for the services provided and the premises are well laid out to clearly separate the various departments.

Inspector's evidence

The pharmacy was situated in a unit within a business park. The pharmacy unit was spacious and comprised of an open area for the pharmacy team and a separate compounding laboratory. The open pharmacy area consisted of a dispensing desk, a checking desk, and a separate dispatch area. The pharmacy stocked a small range of licensed medicines stored in a lockable cabinet. A sink was available within the laboratory and the required contamination-minimising clothing, including lab coats, hair nets, face masks and gloves, were stored nearby for easy access. There was a suitable storage cupboard for flammable items and other ingredients used in the compounding process. The ambient temperature was suitable for the storage of medicines. The pharmacy team had use of a staff area with hand wash basins. The pharmacy was secured against unauthorised access.

The pharmacy unit was cleaned daily. The laboratory was cleaned by the dispenser and the open pharmacy area was cleaned by an external provider. Cleaning involved vacuuming, mopping, and wiping surfaces with alcohol solution.

Members of the public were not able to select or purchase medicines via the pharmacy's website (cchemist.com), but the option to purchase the genomic test for the hair loss treatment service was available. The website displayed the name of the SI and the pharmacy's registration details. It also provided a complaints policy and had a 'contact us' page.

Principle 4 - Services ✔ Standards met

Summary findings

The pharmacy generally provides its services safely and manages them well. It gets its medicines and ingredients from reputable sources and stores them appropriately. And the team has robust processes in place to check the suitability of ingredients and compounded medicines.

Inspector's evidence

Services were advertised on the pharmacy's website. People were able to contact the pharmacy via the website, by telephone or by email.

The pharmacy offered an in-house private prescribing service for hair loss treatment which was led by the PIP. For this service, people completed a self-assessment questionnaire and were provided with a genomic test. The test results and completed questionnaires were reviewed by the PIP, who checked the persons ID and provided a treatment plan. The pharmacy also worked with trichologists who carried out face-to-face consultations and referred people to the pharmacy for genomic testing and treatment.

The pharmacy had an electronic platform through which they received prescriptions from external clinics and communicated with the prescribers. The pharmacy received most of their prescriptions from external CQC registered clinics. The platform allowed prescribers to issue any product, but the SI reported that the pharmacy had not received a prescription for anything very unusual. Once the pharmacy received a prescription, the RP entered details of the prescription onto a compounding software. The compounding software helped create formulas with assay percentages accounted for and adjusted according to assay purity percentage. The pharmacy kept a supply of pre-prepared compounded medicines that were commonly prescribed and had a procedure for highlighting any new prescriptions that required compounding. All pre-prepared compounded medicines were stored in a lockable cupboard and dispensed within 24 hours. All prescriptions were uploaded onto the patient medication record (PMR) system and the RP conducted a legal and clinical check. The RP provided an example of a doctor prescribing an unusual concentration in a formula, which the pharmacist had queried and obtained evidence that it was a recognised formula before dispensing it.

All stock received by the pharmacy was entered onto the system by the pharmacists and included details of the products expiry date and batch number. During the compounding process, the dispenser scanned each ingredient and the weighing scales used were linked to the system so measurements did not need to be recorded manually. When the compounding was complete, the pharmacist quality checked the appearance of the products before signing off. New formulations were quality tested over a few days before launching a new product. Medicines were packed in tamper-evident packaging. The pharmacy used the Royal Mail tracked service and customers had the option of choosing between the 24- and 48-hour special delivery. If a person was not home, packages were returned to the Royal Mail sorting office. Signatures from people were only obtained if medicines were being delivered to the Channel Islands to declare the medicine had been received. Patient information leaflets were supplied to people using the service, which included details about the pharmacy. The leaflets were produced by the pharmacy drawing on information from summary product characteristics (SPC) of individual medicines used, recent studies and support from Medilink. These covered what the medicine is used for, warnings and precautions, instructions on how to use, side effects, storage, and ingredients. The pharmacy could produce large-print labels for those who required, and the alcohol content of

formulations could be adjusted based on a person's preference without affecting the stability of the product.

The pharmacy used recognised wholesalers to source their medicines and ingredients. It had a validation process in place to ensure that the wholesalers it used were appropriate. This included checking Good Manufacturing Practice certificates, certificates of analysis, certificates of registration, safety data sheets and status of wholesale dealing licence. Expiry date checks were carried out monthly. A sample of medicines was checked, and no expired medicines were found during the inspection. MHRA alerts and recalls were received via email and actioned by the SI but this was not documented. The SI said they would document this moving forward. The pharmacy had a lockable fridge to store medicine that required cold storage. Fridge temperatures were checked and recorded daily; these were within the required range for storing temperature-sensitive medicines.

Principle 5 - Equipment and facilities ✔ Standards met

Summary findings

The pharmacy has the appropriate equipment to provide its services safely. And it protects people's privacy when using its equipment.

Inspector's evidence

The pharmacists had access to and used current and relevant reference sources for clinical checks and providing advice. The pharmacy had lockable cabinets for the storage of medicines, a fridge, and a medicinal waste bin was available. The compounding area was enclosed and ventilated in a laboratory, the SI explained that the area pressure was controlled to protect the products and team members. The laboratory and the fume hood were reviewed annually by an external company to ensure appropriate filtration. Accurate weighing scales were calibrated annually, and an electronic mixer was available for compounding, alongside clean conical measures, beakers, a stirring device and a hot plate. A mechanical pestle and mortar, and a mixing machine for liquids was new and did not yet require calibration, the SI said this would be completed yearly going forward. A crimping machine was used to seal the packaging of cream products. The PPE included hair nets, laboratory coats and shoe covers. And a bubble wrap machine was available for packing the medicines for delivery. Medicine cupboards and computer screens were locked, and confidential paperwork was put away when cleaning took place.

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.