General Pharmaceutical Council

Registered pharmacy inspection report

Pharmacy Name: Roseway Labs, Unit 14, Repton Close, Basildon, Essex, SS13 1LJ

Pharmacy reference: 9012117

Type of pharmacy: Internet

Date of inspection: 23/10/2024

Pharmacy context

This pharmacy provides its services at a distance, and the premises is not accessible to the public. It is located within an industrial park and its main business is compounding unlicensed medicines under a s10 exemption 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, hair loss tonics and medication for men's health.

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 dispensing and specific compounding processes. The records had been signed by team members to show they had read and understood the SOPs.

Pharmacy team members recorded dispensing mistakes that happened before a medicine was supplied (near misses). The pharmacist carried out monthly reviews with the team using a near miss review form to help identify patterns and areas for improvement and took action when appropriate to help prevent mistakes being repeated. For example, some of the actions taken to improve patient safety included separating baskets to avoid batch labels moving across baskets. The pharmacy had processes to record dispensing mistakes where the medicine was handed to a person (dispensing errors). These were documented on a patient safety incident form, which detailed the incident, the cause and actions to be taken to prevent harm and recurrence.

The pharmacy had current professional indemnity insurance. The correct responsible pharmacist (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 largely well maintained although there were some instances where the RP had missed signing out. 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. The superintendent (SI) said that they were in the process of updating the records and agreed that in future this information would be included. The private prescription record was not available at the time of the inspection, but a sample was provided following the inspection.

The pharmacy had completed a thorough risk assessment for the compounding service, which covered contamination, errors, emergencies, health and safety, staff training, raw material, staffing, ID checks, deliveries and more. It was dated April 2024 and was to be reviewed annually. Records of unlicensed medicine supplies were kept electronically and were well maintained.

People were able to give feedback or raise concerns via several means including email, by completing an online 'contact us' form on the pharmacy's website or by leaving an online review. The pharmacy did not have any direct telephone contact with the public, but people could contact the sister branch. The pharmacy kept a complaints log for all customer service complaints. These were triaged to the appropriate person based on the nature of the complaint. The pharmacy took steps to investigate what went wrong if there were complaints about a product, but this was not always well documented. So the pharmacy could not always demonstrate that concerns had been managed appropriately.

All team members completed annual data protection training which covered the General Data

Protection Regulations. The manager had access to check the team's training status and confirmed they were up to date. There was also a data protection SOP, which the team has read and signed. Individual pin numbers and passwords were used to access the pharmacy's electronic system. The pharmacy had recently started a password audit to help strengthen security around passwords and access to confidential information. The premises were not accessible to members of the public which helped in protecting confidential information. Confidential waste was shredded or separated for collection by an appropriate contractor for destruction.

The pharmacists had completed level three safeguarding training. The pharmacist said they would raise concerns to the SI or local safeguarding boards. The rest of the team had not been provided with safeguarding training, but they did not have access to members of the public so safeguarding concerns were unlikely to arise.

Principle 2 - Staffing ✔ Standards met

Summary findings

The pharmacy has enough 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 two regular pharmacists, one of whom was the manager, two trained dispensers, one trainee dispenser, five compounders and two dispatch assistants. Team members said there was sufficient staff cover for the services provided. All compounders involved in the preparation of unlicensed medicines had completed in-house training. The manager said they would also be enrolled onto a manufacturing training module from an external training provider. All dispensers and pharmacists were also trained in compounding and using the equipment, so they could cover different roles when other members of staff were off.

The manager had completed a compounding course from an external training provider. And the second pharmacist was in the process of completing in-house training. Educational webinars and updates were available to the pharmacists and dispensers via a shared platform. Team members received notifications when new webinars were uploaded onto the platform. The manager also provided educational quizzes to the team to engage them and support their ongoing training. And team members had access to compounding reference sources, the pharmacists, and the SI to help resolve queries.

Formal appraisals were carried out annually with all members of the team. Targets were set based on personal performance. The targets were focused on improving proficiency and competence, such as reducing errors and completing courses within a specified time frame. Team members said they worked in an open environment and were able to raise concerns to the pharmacists, SI or senior managers. And they were able to share information and communicate with team members from the other branch via the electronic platform. The SI visited the branch each week to review complaints and make improvements, such as making the complaints process more efficient. Team meetings were held monthly to discuss near misses. And the manager attended monthly meetings at head office to discuss recent issues and updates, which were relayed to the team.

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 warehouse within an industrial park. The entrance of the warehouse led to a reception area, which led to the pharmacy's operational area. The doors of the warehouse were kept locked throughout the day and a bell was fitted at the door. The pharmacy unit was spacious and comprised of several compounding units, an open area for the pharmacy team, and another area for the dispatch team. The team also had access to a clean, spacious staff room. And there was a separate room for compounding allergen containing products, with clear signage on the door to highlight this was an allergy room. The pharmacy was secured against unauthorised access. Fire exits were kept clear and fire extinguishers were available.

Compounded medicines were prepared in designated laminar flow cabinets. The ambient temperature was suitable for the storage of medicines. The compounding units were cleaned twice a week and equipment and the counters were wiped daily. Team members were seen cleaning equipment and surfaces after use. The pharmacy had a separate washroom to clean the compounding equipment. The allergy room was used to prepare only one product at a time and all equipment and surfaces were thoroughly cleaned between each product, using disposable wipes and alcohol disinfectant, to avoid cross-contamination.

The pharmacy had a website (rosewaylabs.com) where returning customers could order their repeat medication. But the website mostly provided information about the sister branch as this was where the customer service team were based.

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 generally stores them appropriately. And the team has robust processes in place to check the suitability of ingredients and compounded medicines.

Inspector's evidence

The pharmacy promoted its services through its website, by visiting doctors' practices and by exhibiting at trade exhibitions. The pharmacy supplied medication to people in the UK, Ireland and sometimes other countries. It had a list of countries that it would not supply medicines to.

The pharmacy had an electronic platform through which they received prescriptions. Prescribers had individual logins and the team received notifications to alert them when new prescriptions were issued. Prescribers underwent an onboarding process by head office, who carried out checks to ensure they were appropriate prescribers for the service. The platform had set formulas for prescribers to choose from and could make slight amendments if needed. Once the pharmacy received a prescription, the pharmacists conducted a legal and clinical check. Prescriptions could not be processed until a clinical check had been carried out. The system flagged prescriptions for new formulas so the pharmacists could review what was required.

Colour-coded baskets were used throughout the dispensing process to differentiate between products. Patient information leaflets were supplied with all medicines, including compounded medicines. These included information on the active ingredients, how to take the medicine, potential side effects, storage and how to report side effects. The pharmacists said that they would contact the prescriber if they had any queries about a prescription. Interventions were documented on the person's electronic record. Pharmacists contacted the prescribers, mostly by email and sometimes by telephone. The pharmacist showed an example of a doctor prescribing an oral medicine to be used off-label, which the pharmacist had queried this and obtained evidence that it was a recognised use 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. When preparing compounded products, the compounders entered the details of the ingredients they used on the system. The system alerted the team if they had entered an incorrect batch number or expiry date. This ensured the correct ingredients were used and that the compounders did not select expired products. Safeguards were also in place to ensure accurate measurements were made. When the compounding was complete, the pharmacist checked the quantities and equipment used against the formula, the weight of the capsules and the appearance of the products before signing off. Each step of the process was signed by the individual involved using their personal pin, so clear audit trails were maintained for all steps involved in compounding. All batches were quality tested by the pharmacists.

Once the medicines had been dispensed and checked by the pharmacist, they were sent to the dispatch team. Medicines were packed in tamper-evident packaging. Fragile items were packed in hive wrap and placed in double padded envelopes. The pharmacy used the Royal Mail signed-for service and customers received a link to track their package. If a package was returned, the pharmacy made a record and contacted both the person and their prescriber to inform them. The medicine would be

disposed of.

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, and safety data sheets. The pharmacy stored its compounding ingredients in a separate storage room. And it stored a small range of licenced medicines in a separate section to the compounded medicines. All compounded medicines were marked with their batch number and expiry date. Expiry date checks were carried out weekly and documented. Two out of dates were found during the inspection. These were removed and disposed of. MHRA alerts and recalls were received from head office, printed actioned and filed. Fridge temperatures were checked and recorded daily; these were within the required range for storing temperature-sensitive medicines. Compounded medicines containing allergens were stored on a separate shelf in the fridge.

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 pharmacy used a range of equipment to prepare its unlicensed medicines, these included: laminar flow cabinets, scales, beakers, measuring cylinders, disposable syringes and heat plates. Equipment was serviced and PAT-tested annually. Balances were calibrated daily and serviced annually. The compounding pods were serviced annually to check for cleanliness and contamination. Team members wore personal protective equipment when compounding, including face masks, hair nets, lab coats and gloves. Computers were password protected. Up to date reference sources were available including BNF and access to scientific journals.

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.